US011504238B2

(12) **United States Patent**
Lashinski

(10) **Patent No.: US 11,504,238 B2**
(45) **Date of Patent: *Nov. 22, 2022**

(54) **MITRAL VALVE INVERSION PROSTHESES**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **17/081,128**

(22) Filed: **Oct. 27, 2020**

(65) **Prior Publication Data**

US 2021/0038388 A1 Feb. 11, 2021

Related U.S. Application Data

(63) Continuation of application No. 15/423,374, filed on Feb. 2, 2017, now Pat. No. 10,849,755, which is a continuation-in-part of application No. 14/427,909, filed as application No. PCT/US2013/059751 on Sep. 13, 2013, now Pat. No. 9,610,156.

(60) Provisional application No. 62/291,347, filed on Feb. 4, 2016, provisional application No. 61/700,989, filed on Sep. 14, 2012.

(51) **Int. Cl.**
A61F 2/24 (2006.01)

(52) **U.S. Cl.**
CPC ***A61F 2/2466*** (2013.01); ***A61F 2/2409*** (2013.01); ***A61F 2/2442*** (2013.01); ***A61F 2/2445*** (2013.01); *A61F 2220/0016* (2013.01); *A61F 2250/0039* (2013.01)

(58) **Field of Classification Search**
CPC A61F 2/2409; A61F 2/2442; A61F 2/2445; A61F 2/2466; A61F 2220/0016; A61F 2250/001; A61F 2250/0039
See application file for complete search history.

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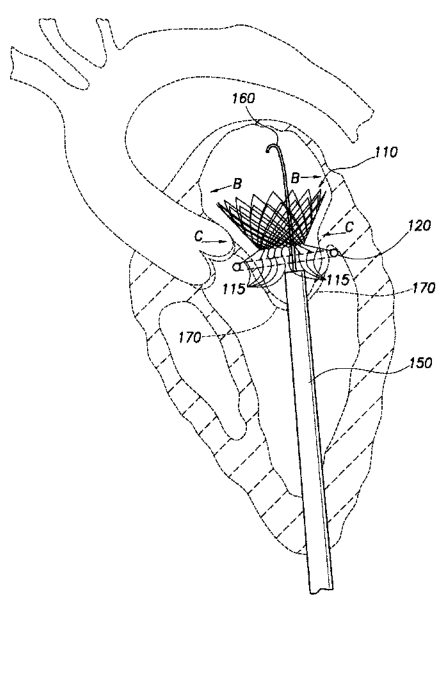
(57) **ABSTRACT**

Systems, devices and methods for resizing a valve annulus are described. An implant is delivered proximate a mitral valve, the implant comprising a tubular body and a plurality of piercing helical anchors, the tubular body comprising an proximal diameter and a distal diameter. Tissue proximate the mitral valve is engaged by rotating the plurality of anchors with corresponding rotational drivers. The tubular body may be transitioned from a first structural configuration having the proximal diameter smaller than the distal diameter to a second structural configuration having the proximal diameter larger than the distal diameter.

19 Claims, 24 Drawing Sheets



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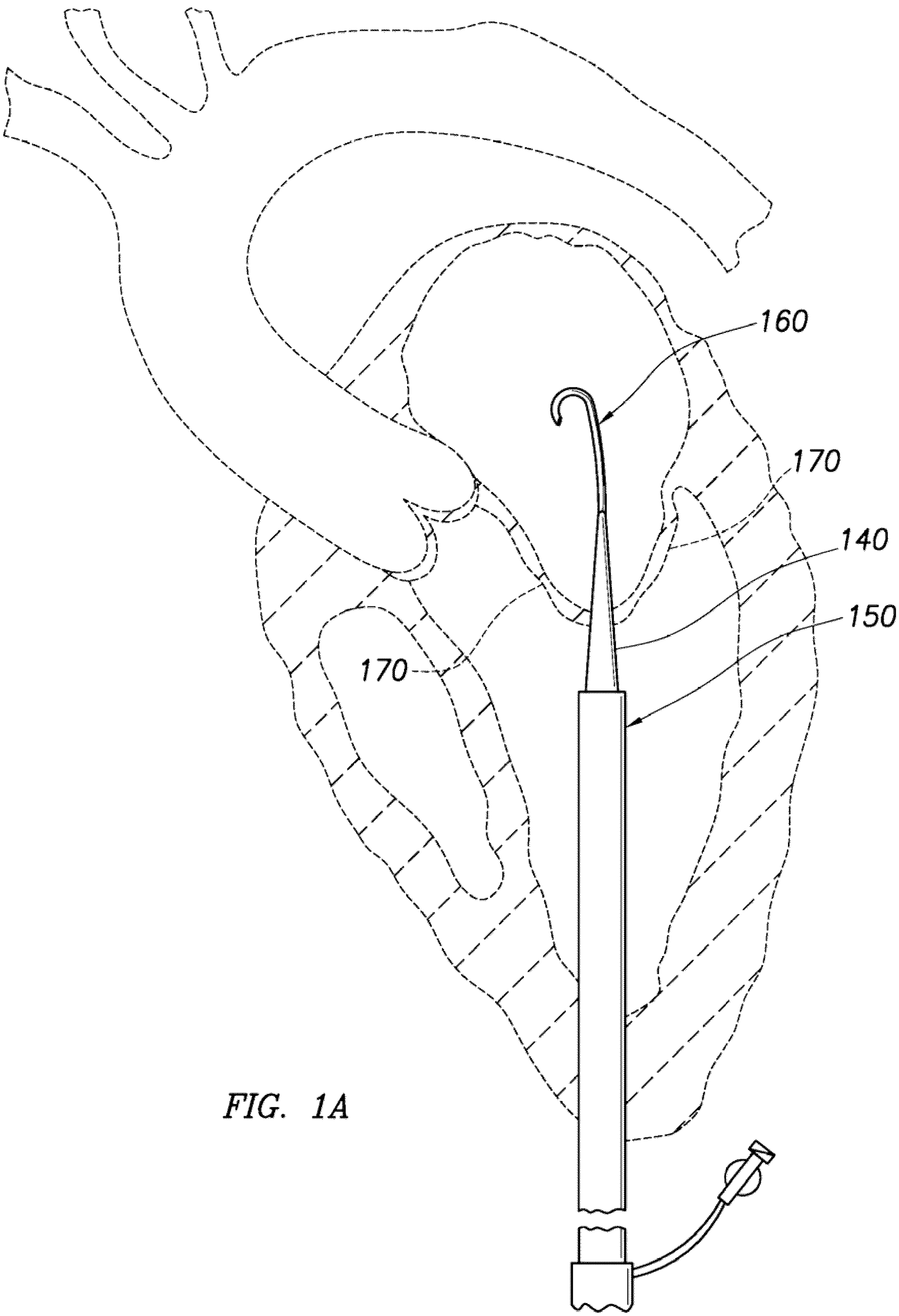


FIG. 1A

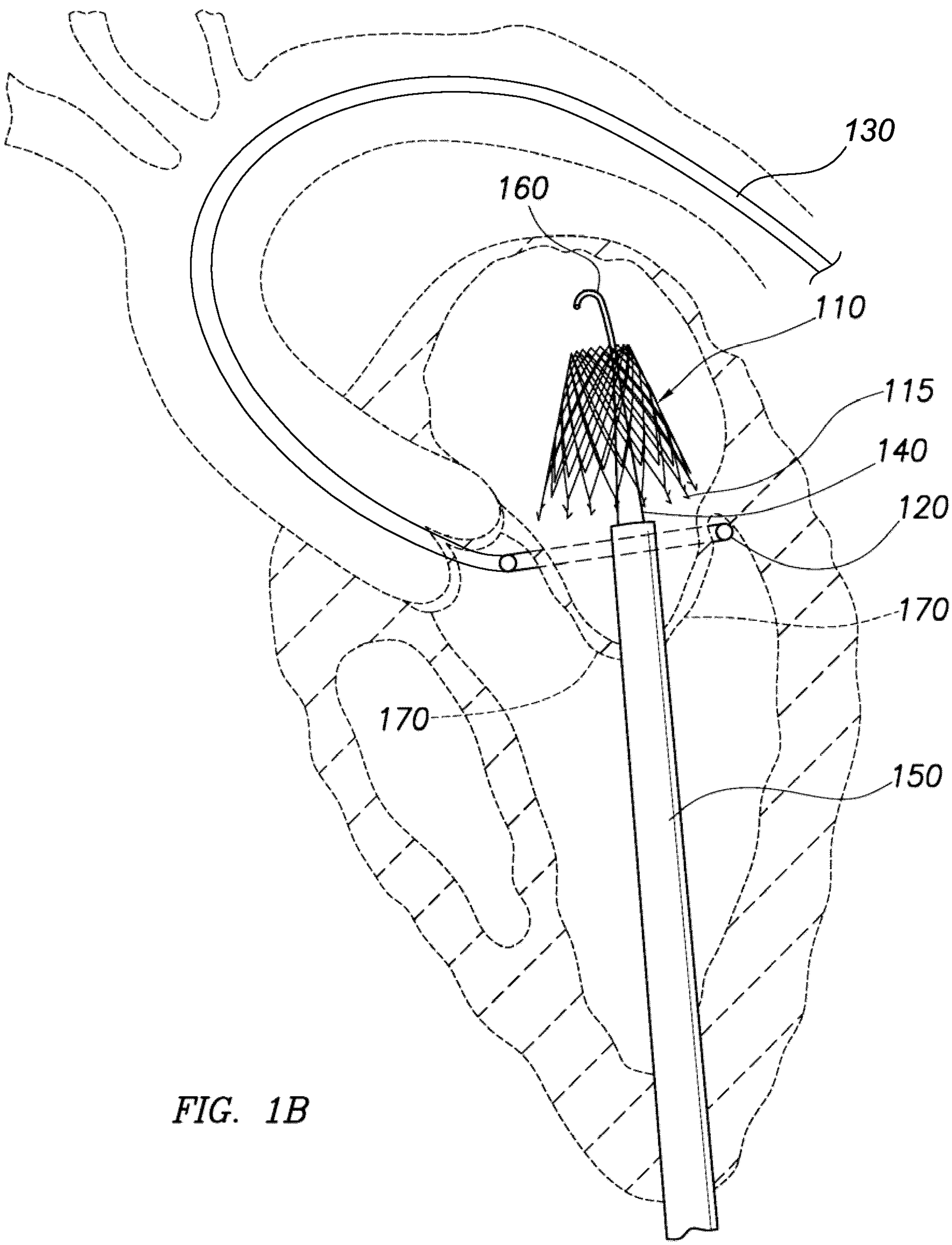


FIG. 1B

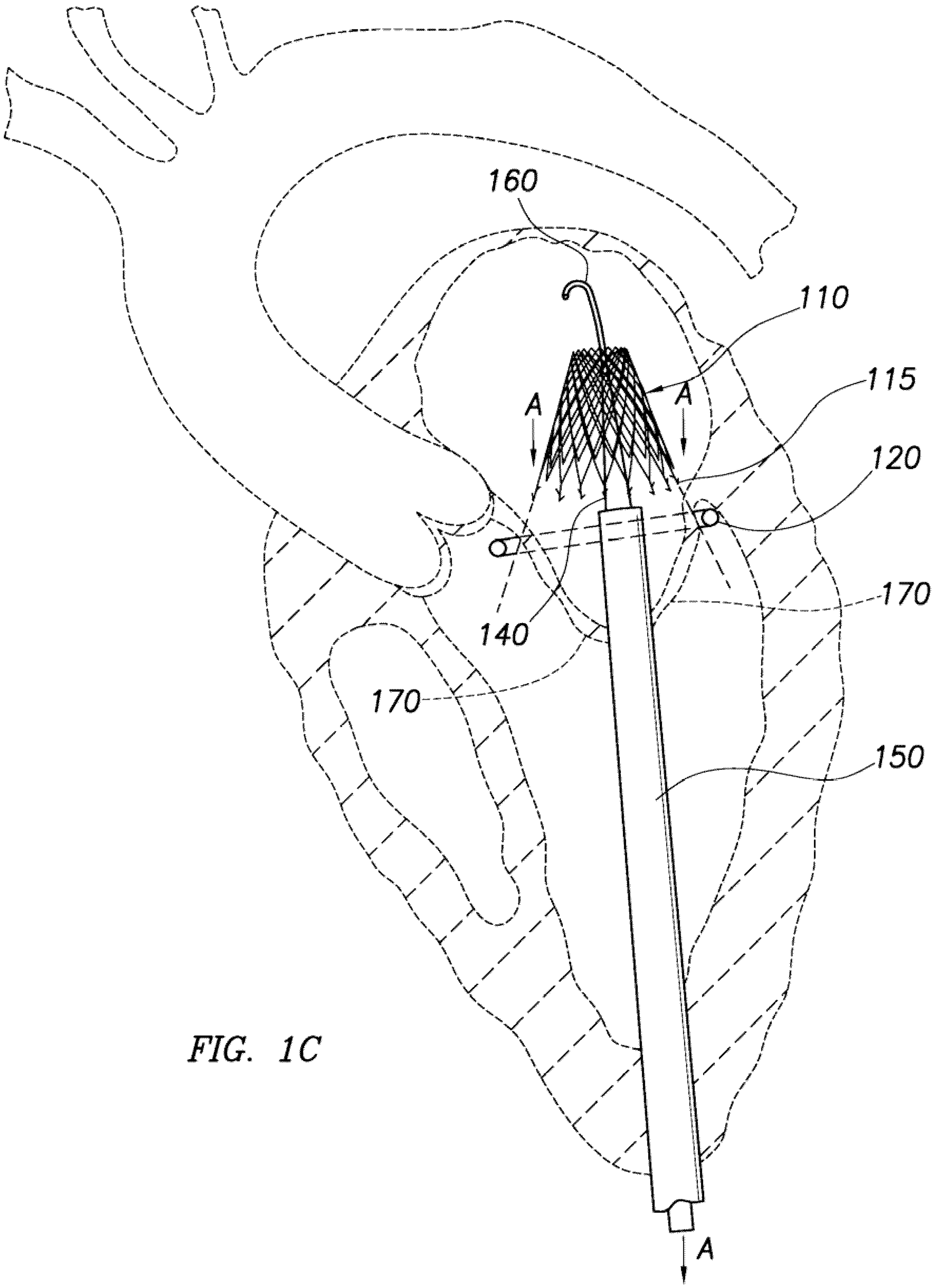


FIG. 1C

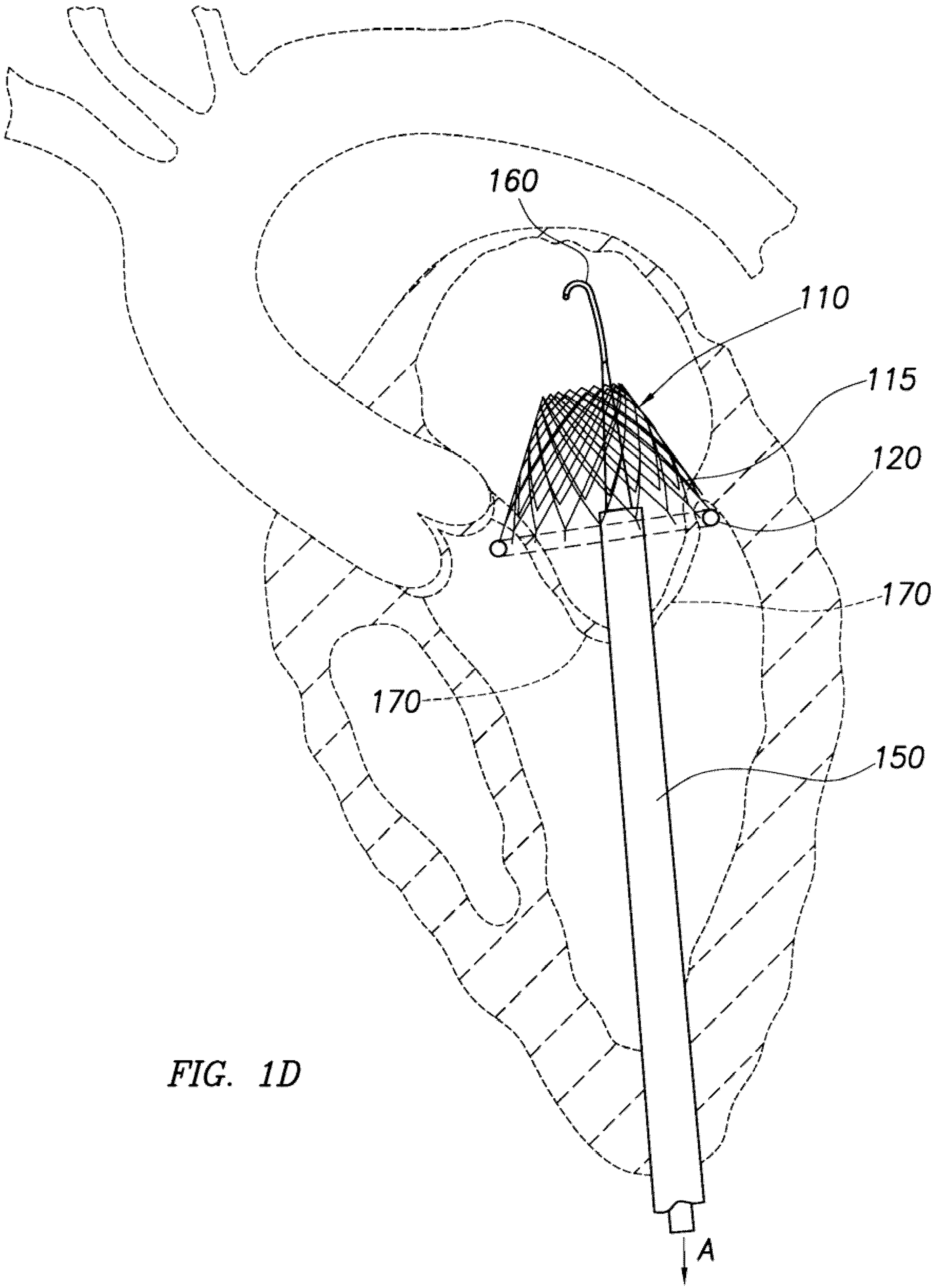


FIG. 1D

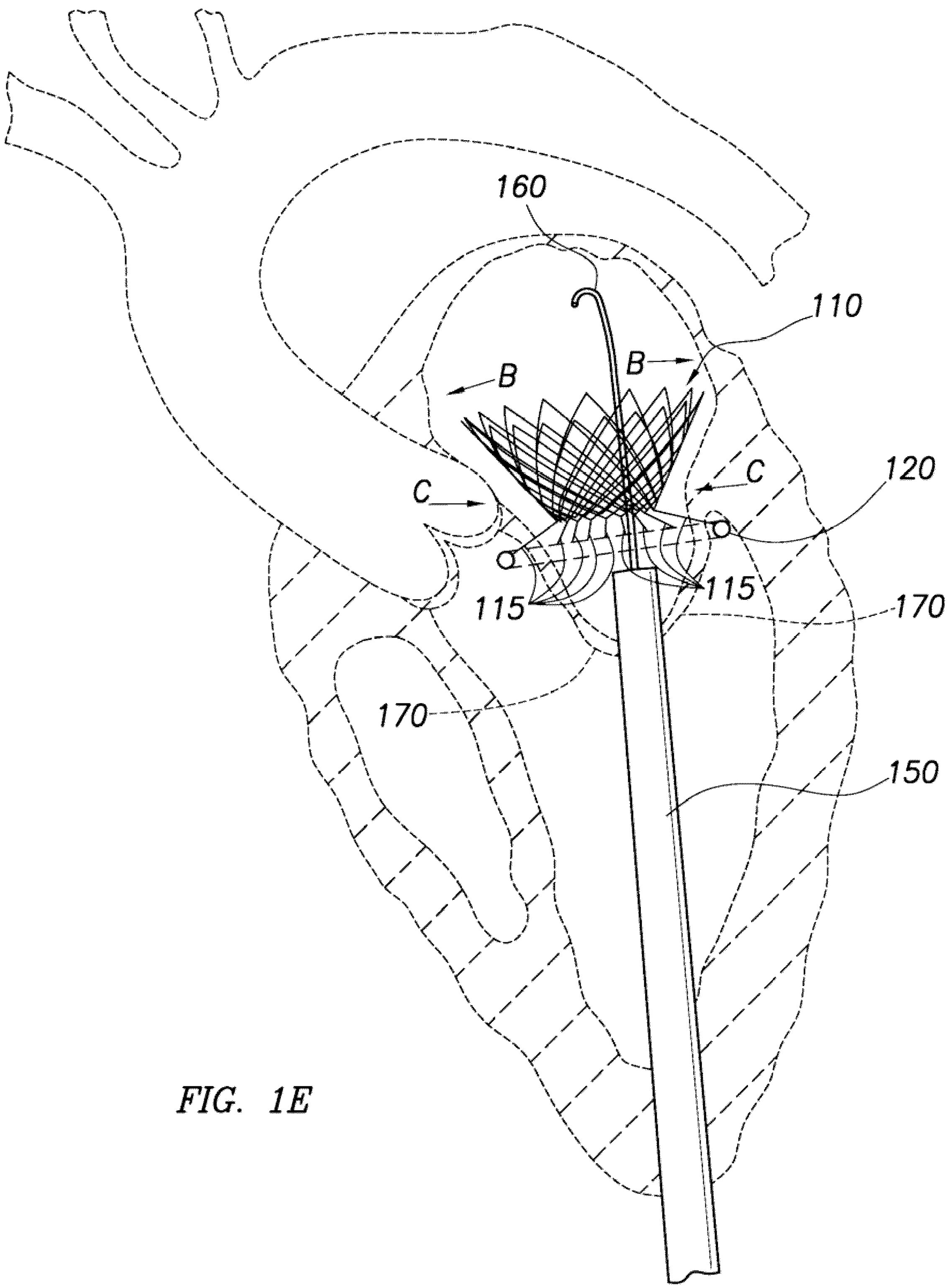


FIG. 1E

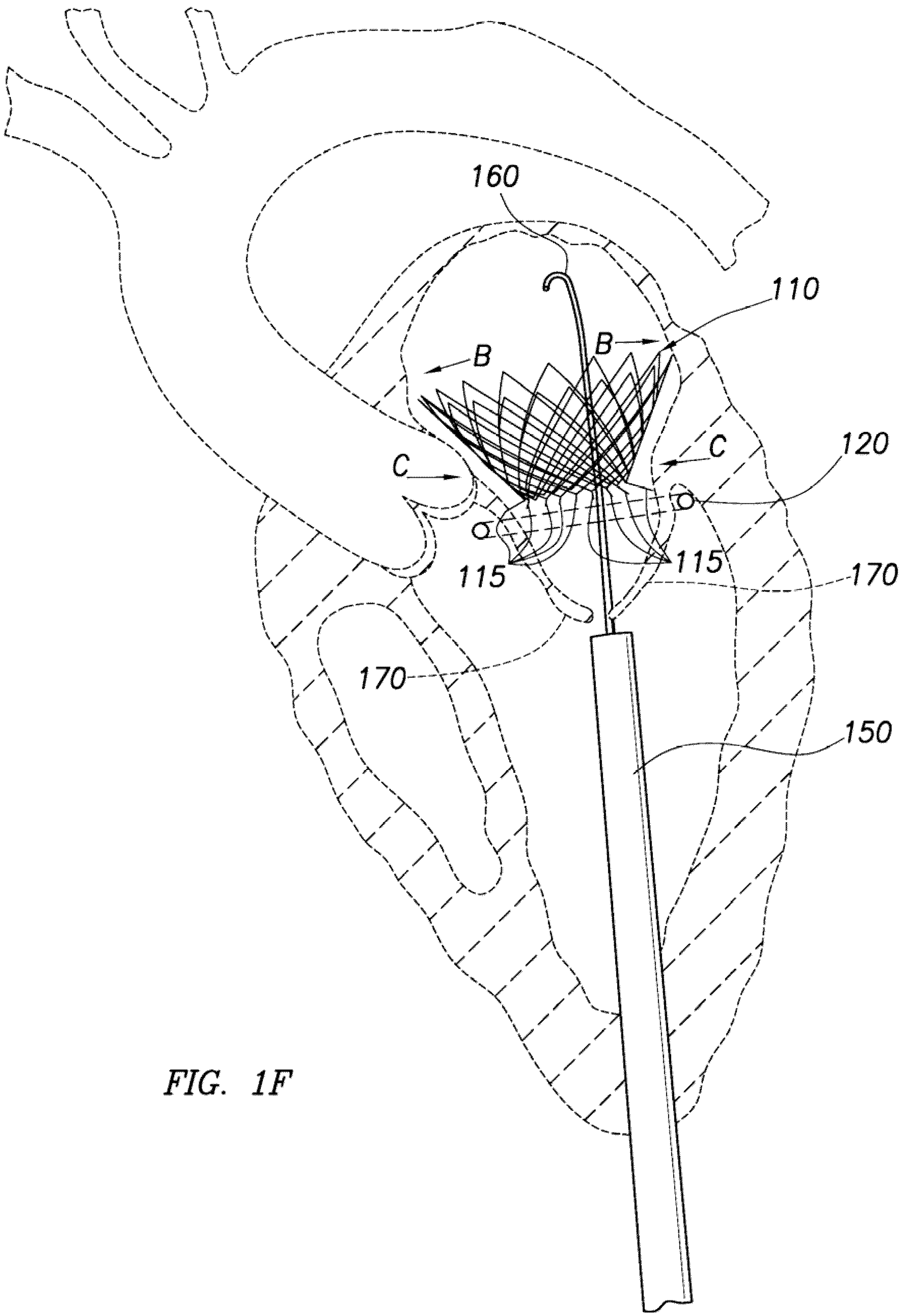
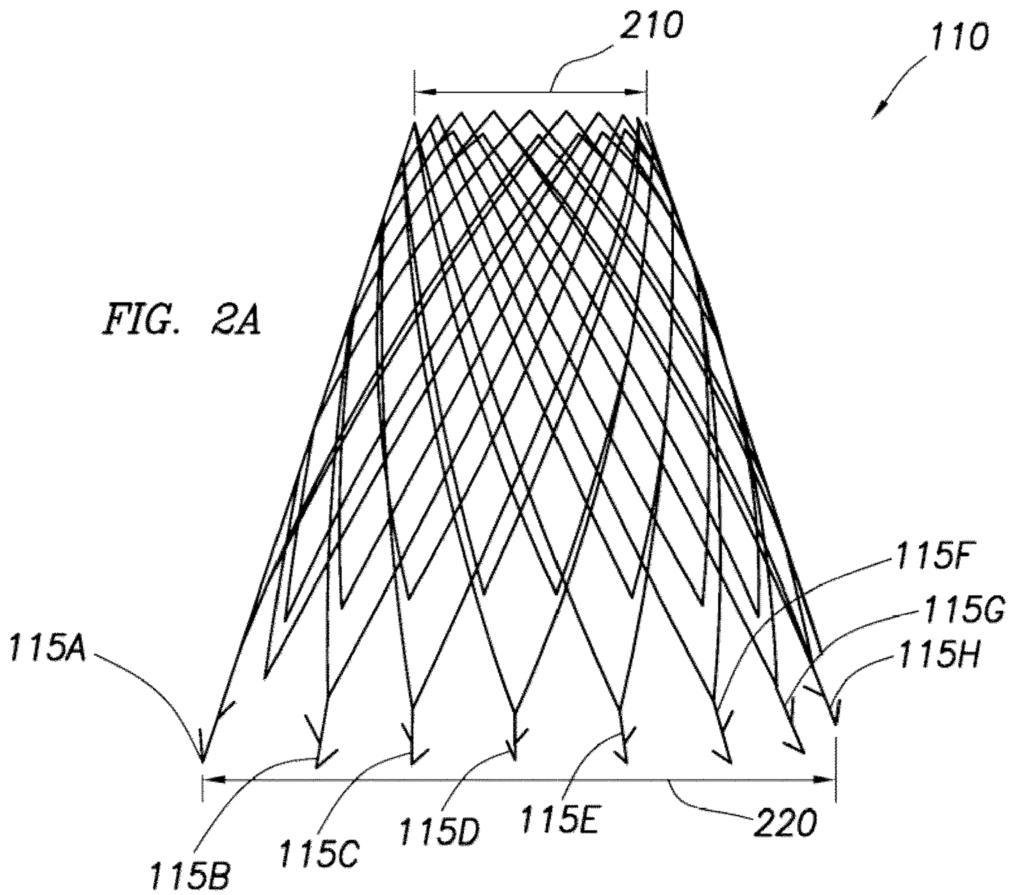


FIG. 1F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110
115F
115G
115H
115A
115B
115C
115D
115E
220

FIG. 2A

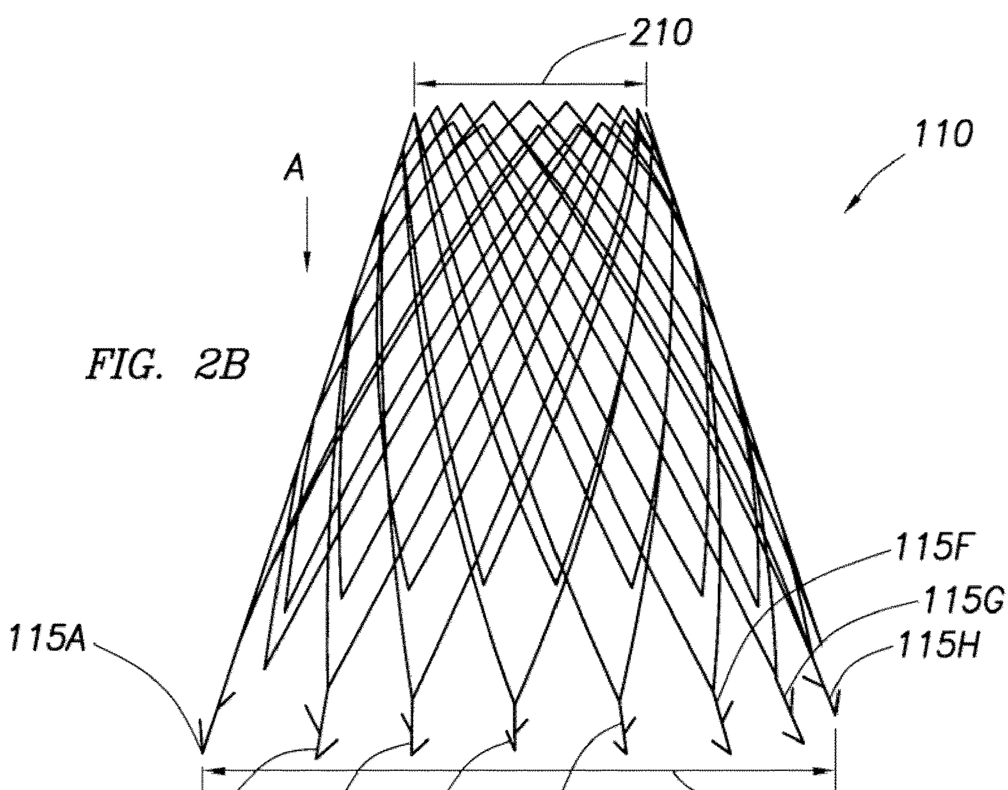
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FIG. 2B

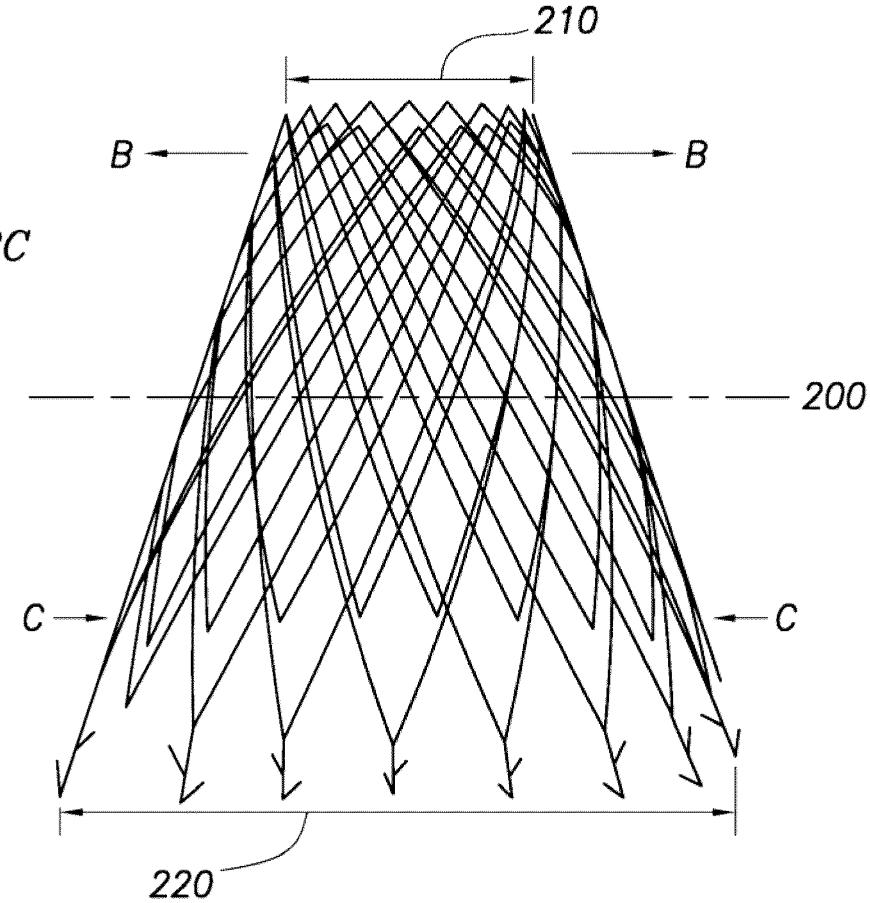


FIG. 2C

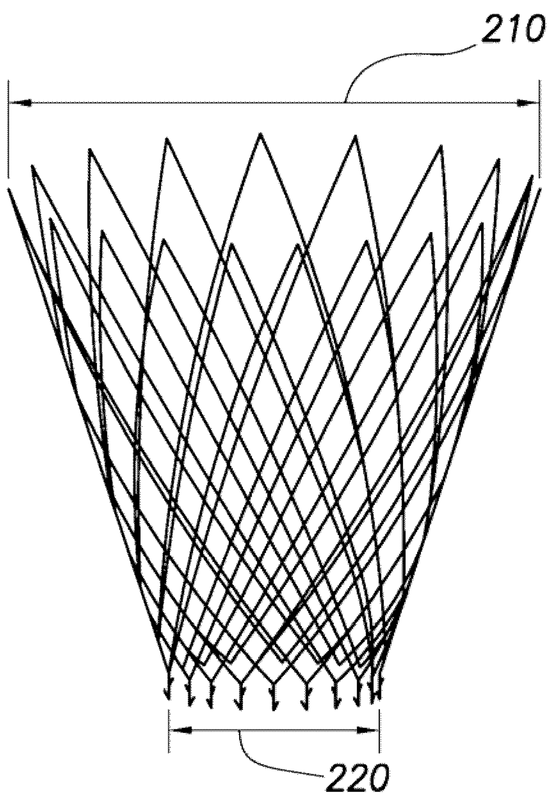


FIG. 2D

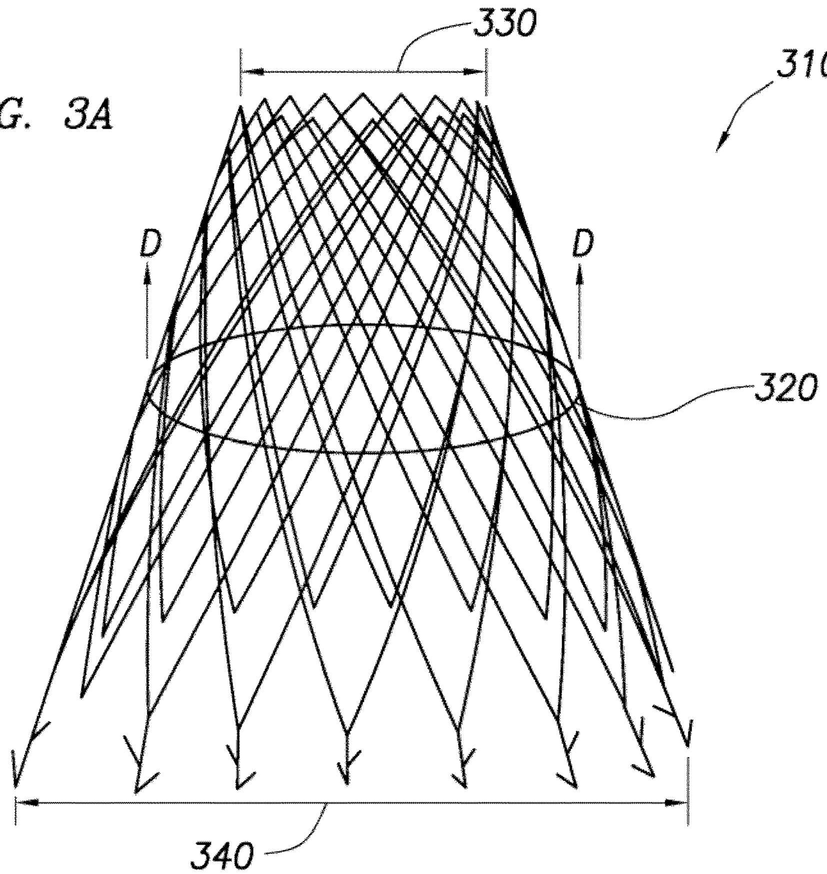


FIG. 3A

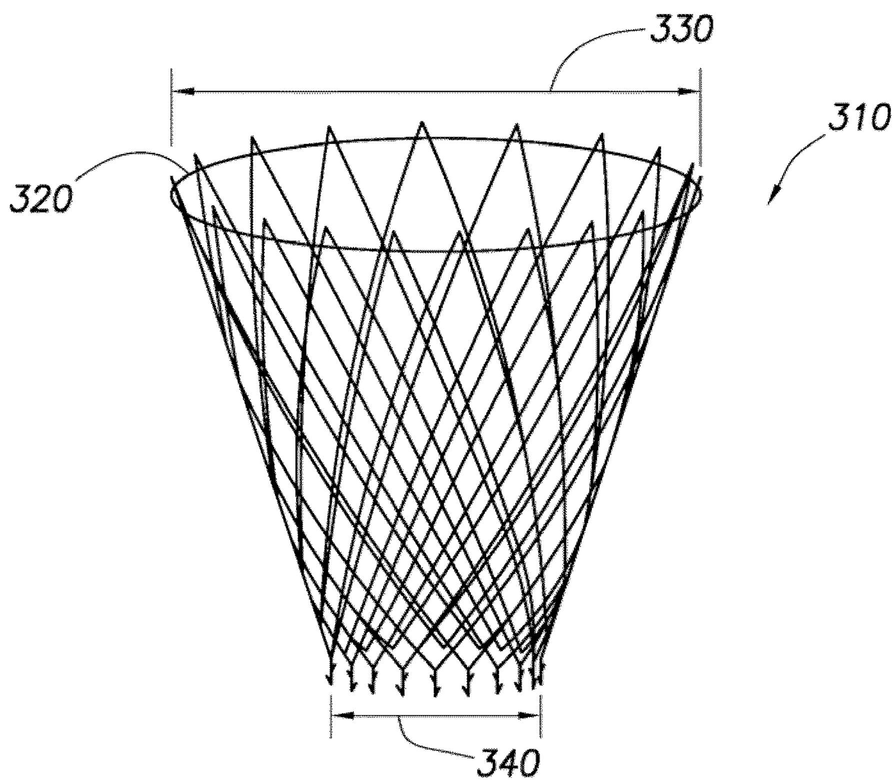
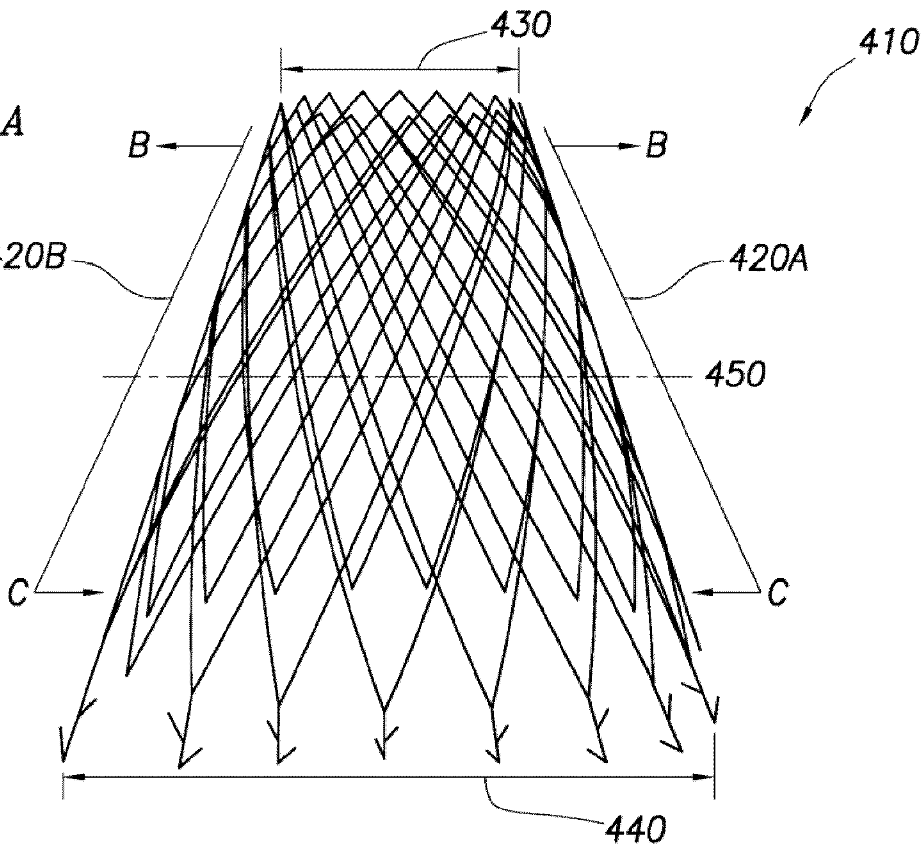


FIG. 3B

FIG. 4A



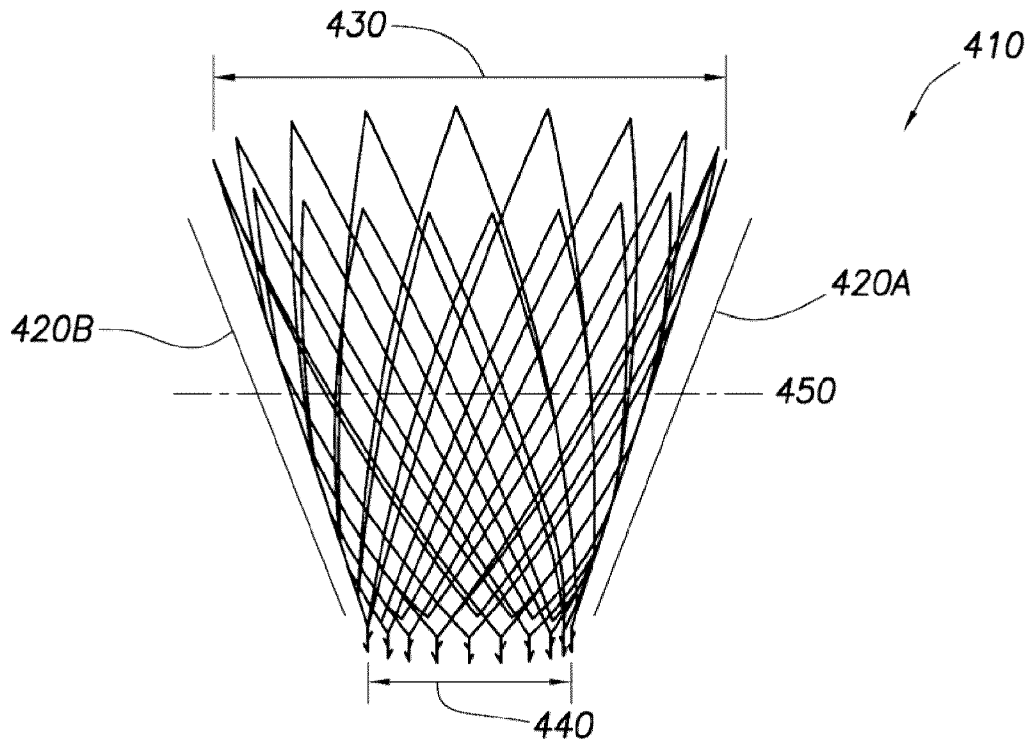


FIG. 4B

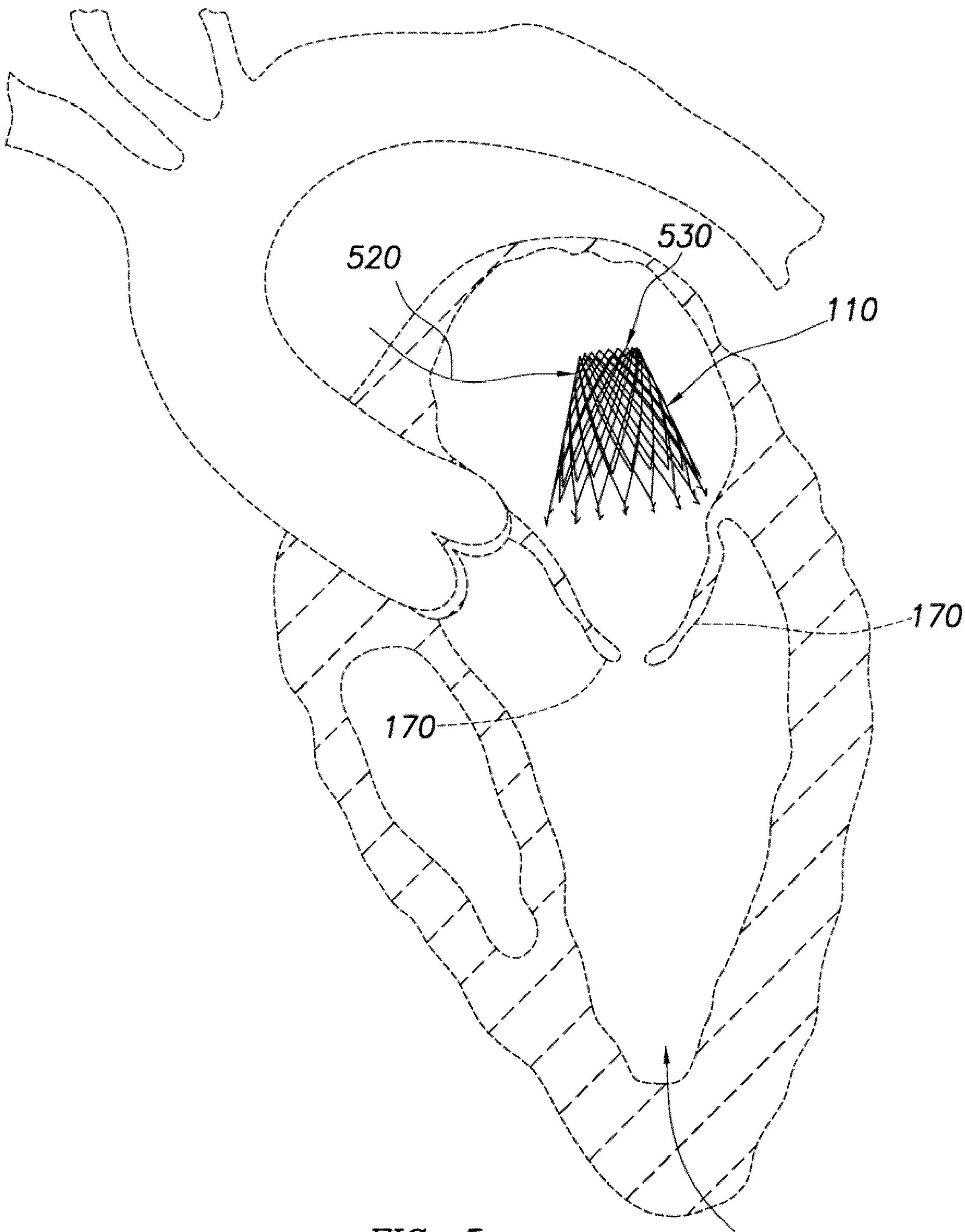


FIG. 5

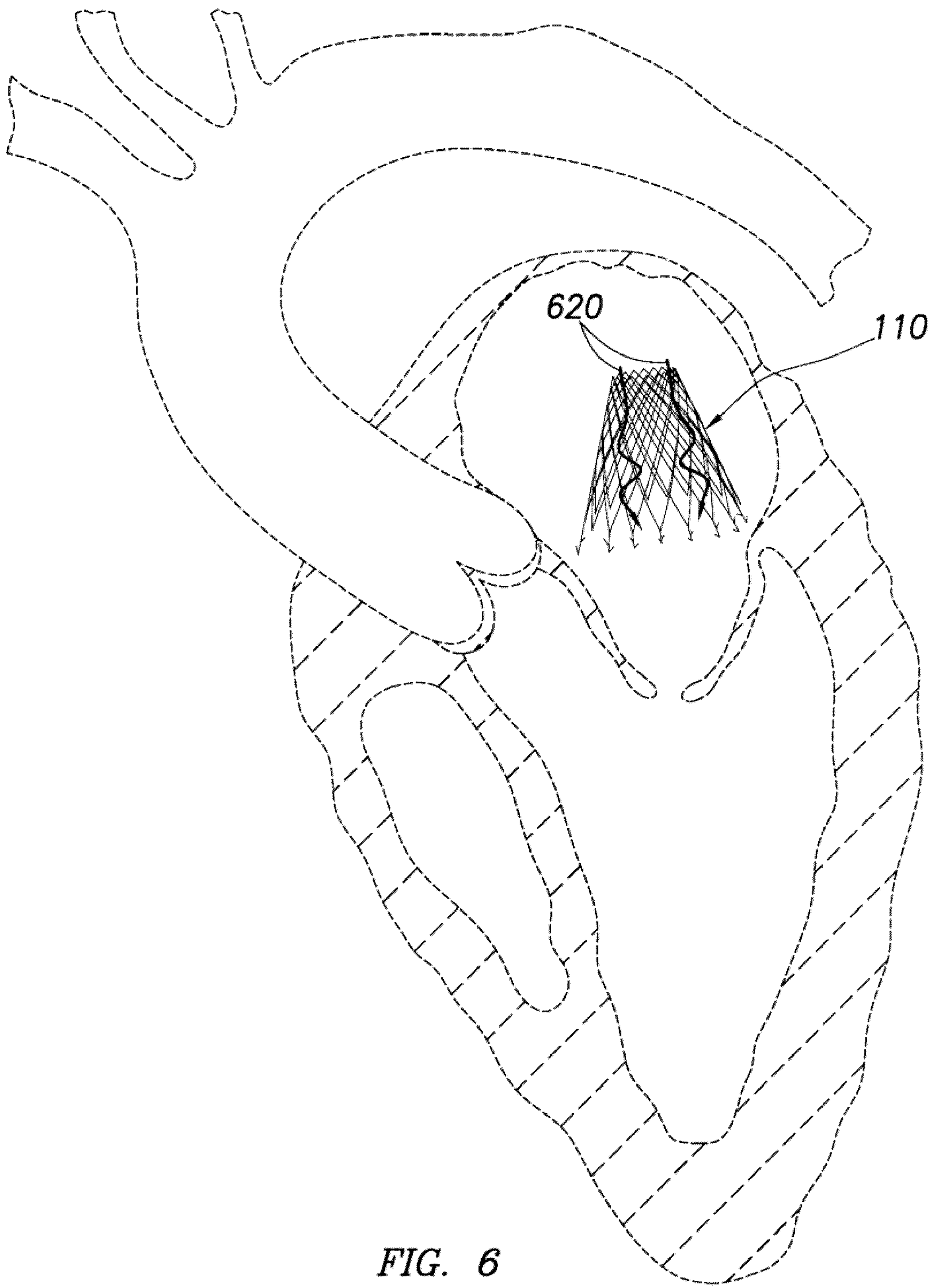


FIG. 6

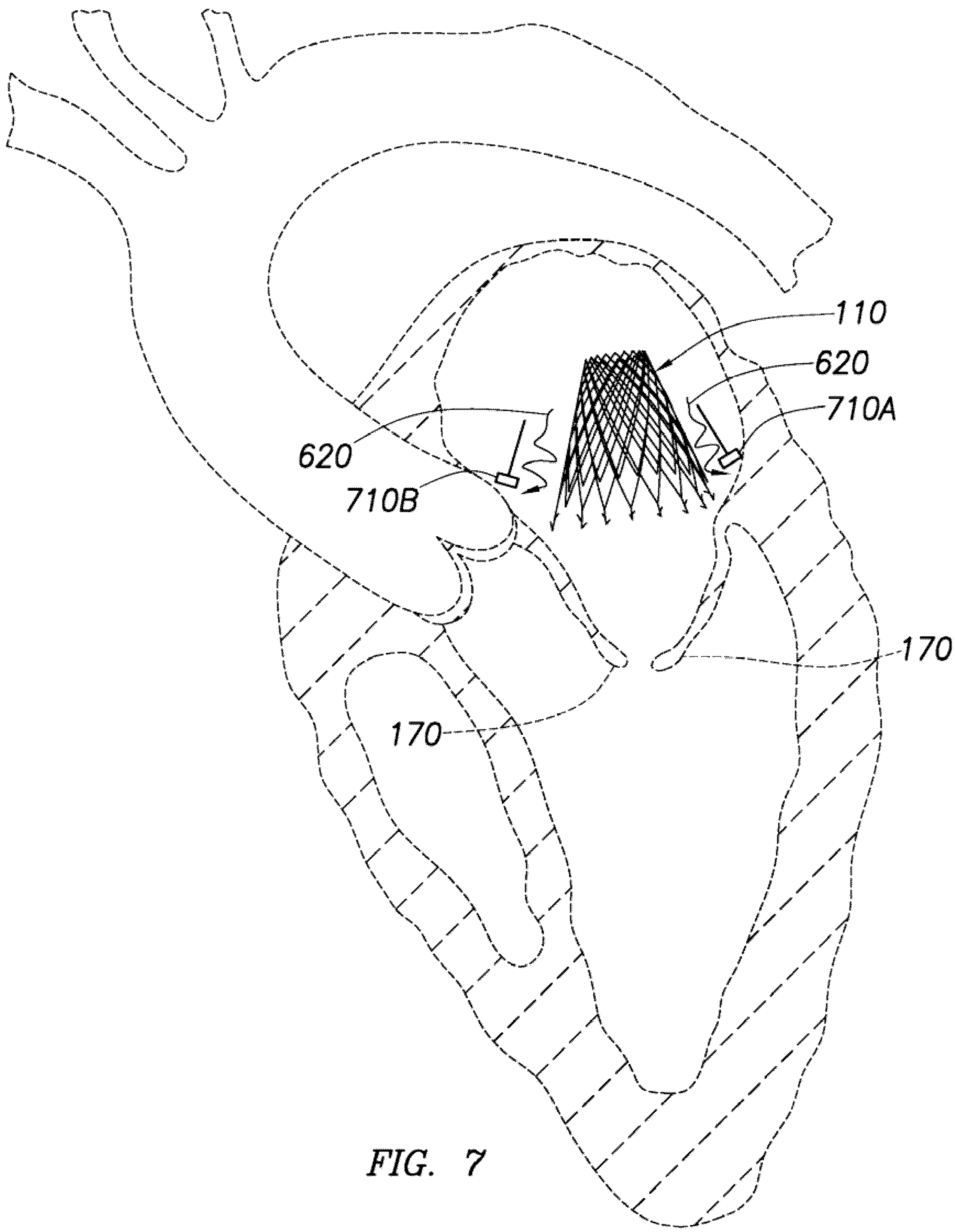


FIG. 7

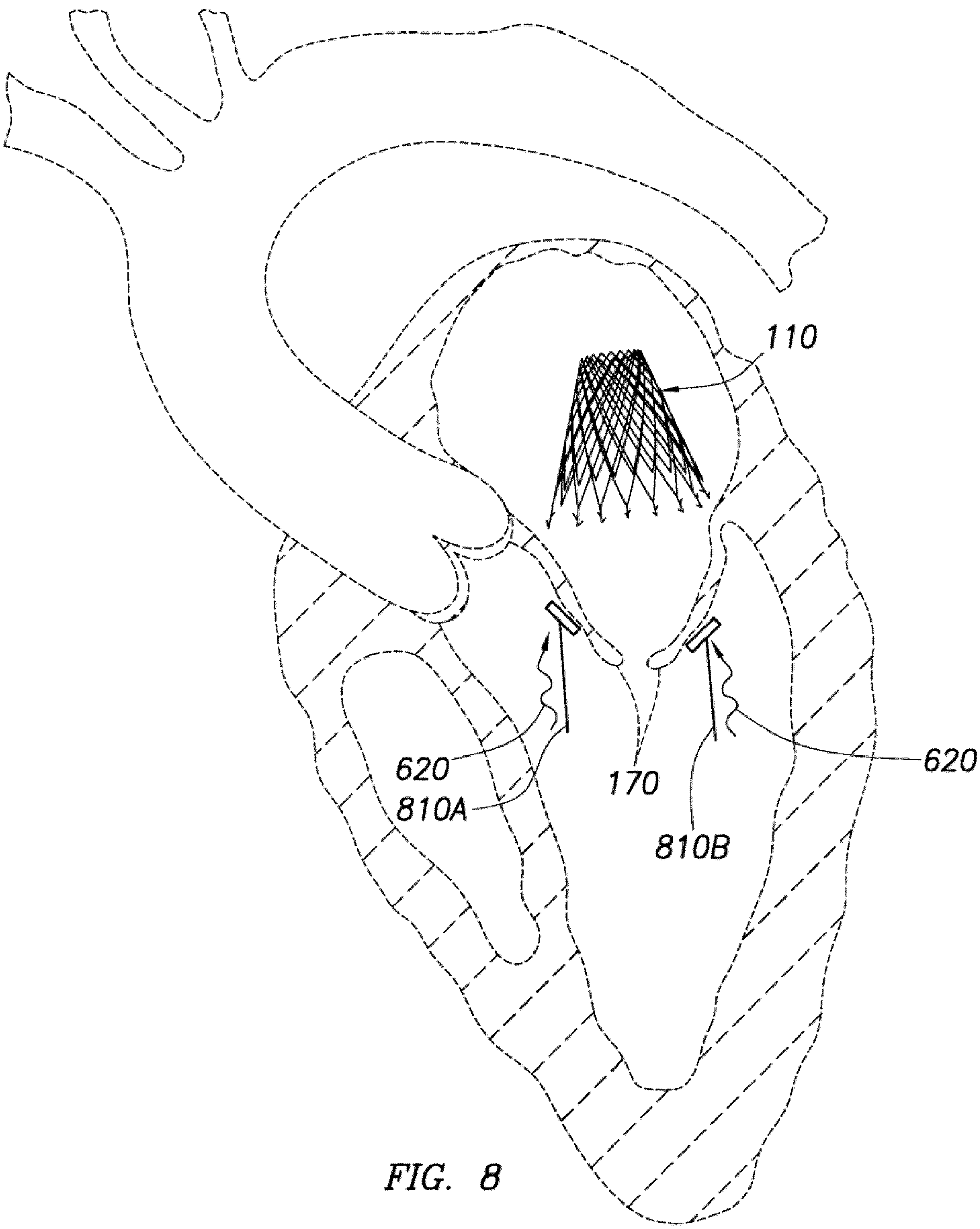


FIG. 8

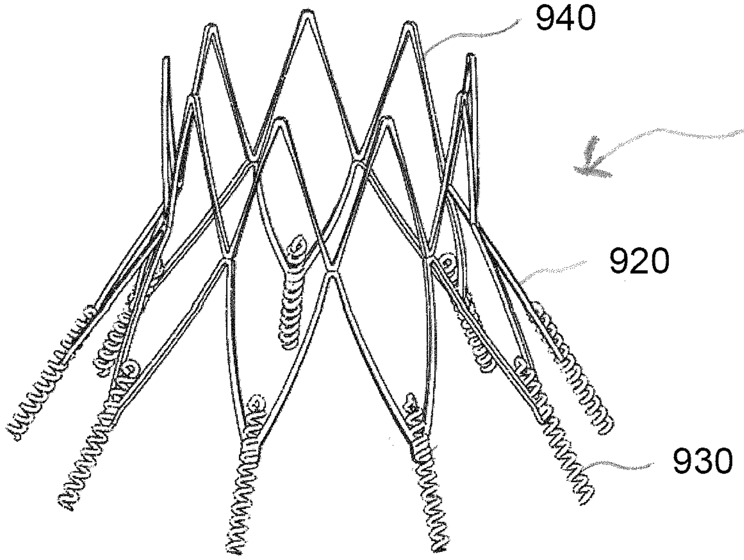


FIG. 9A

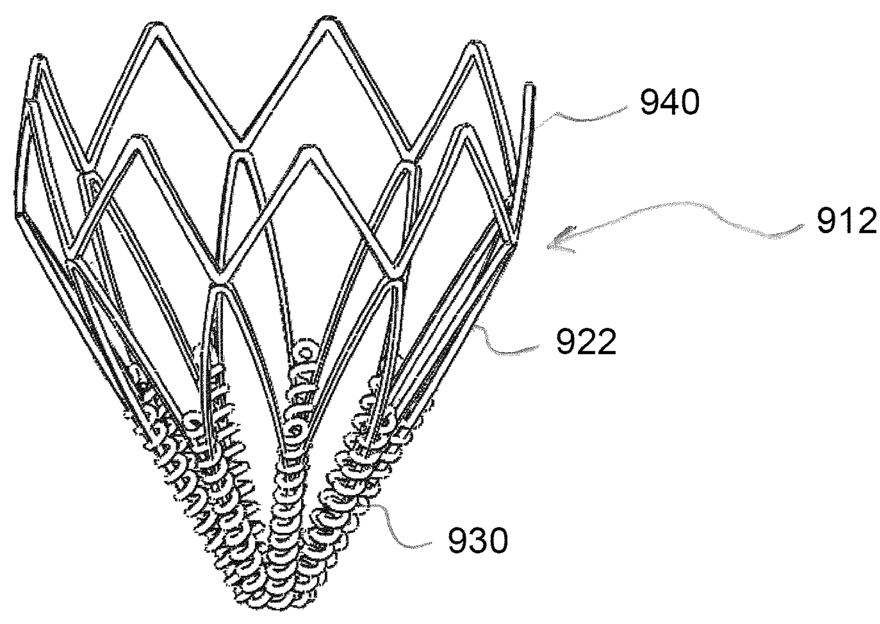


FIG. 9B

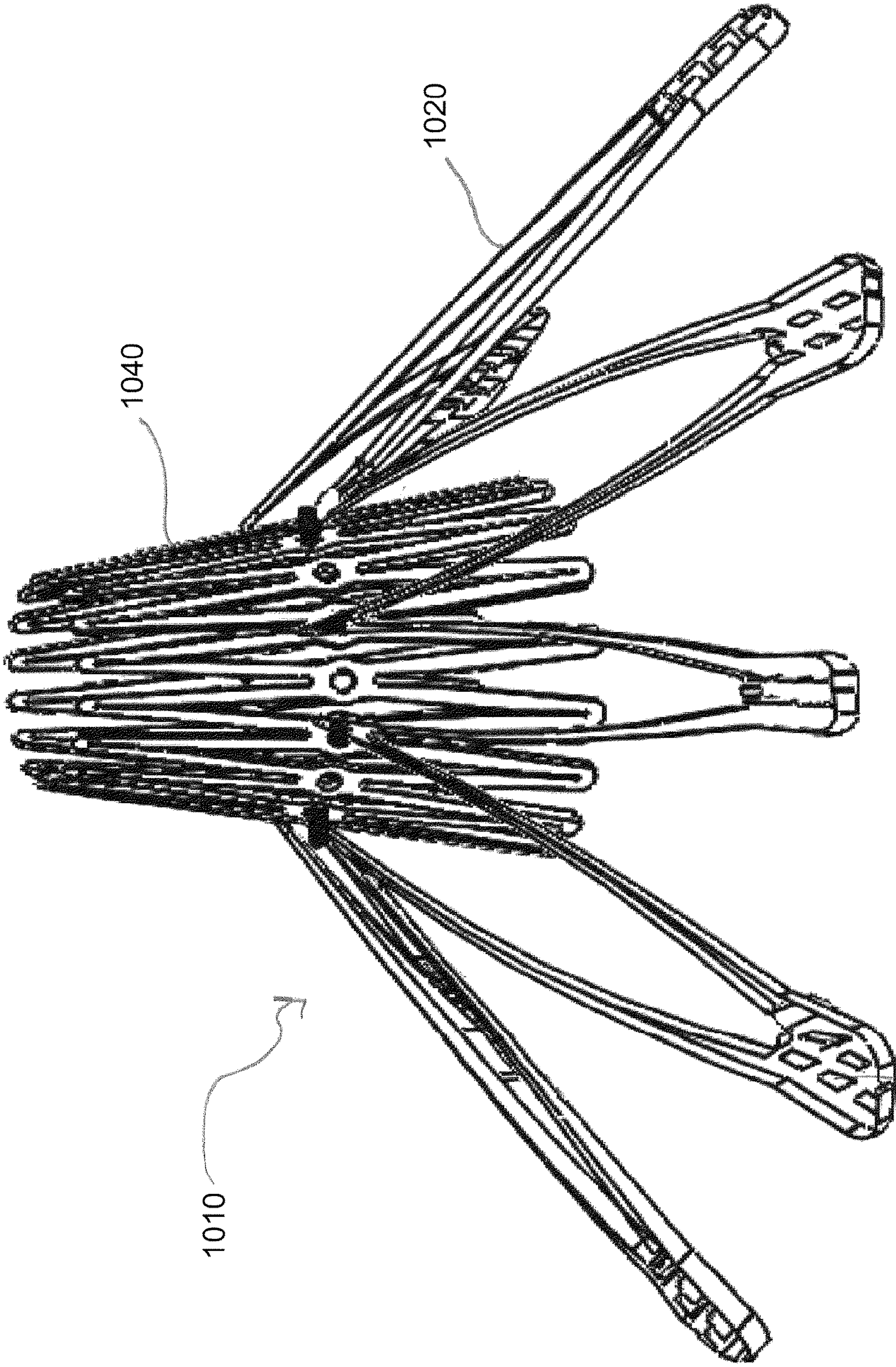


FIG 10

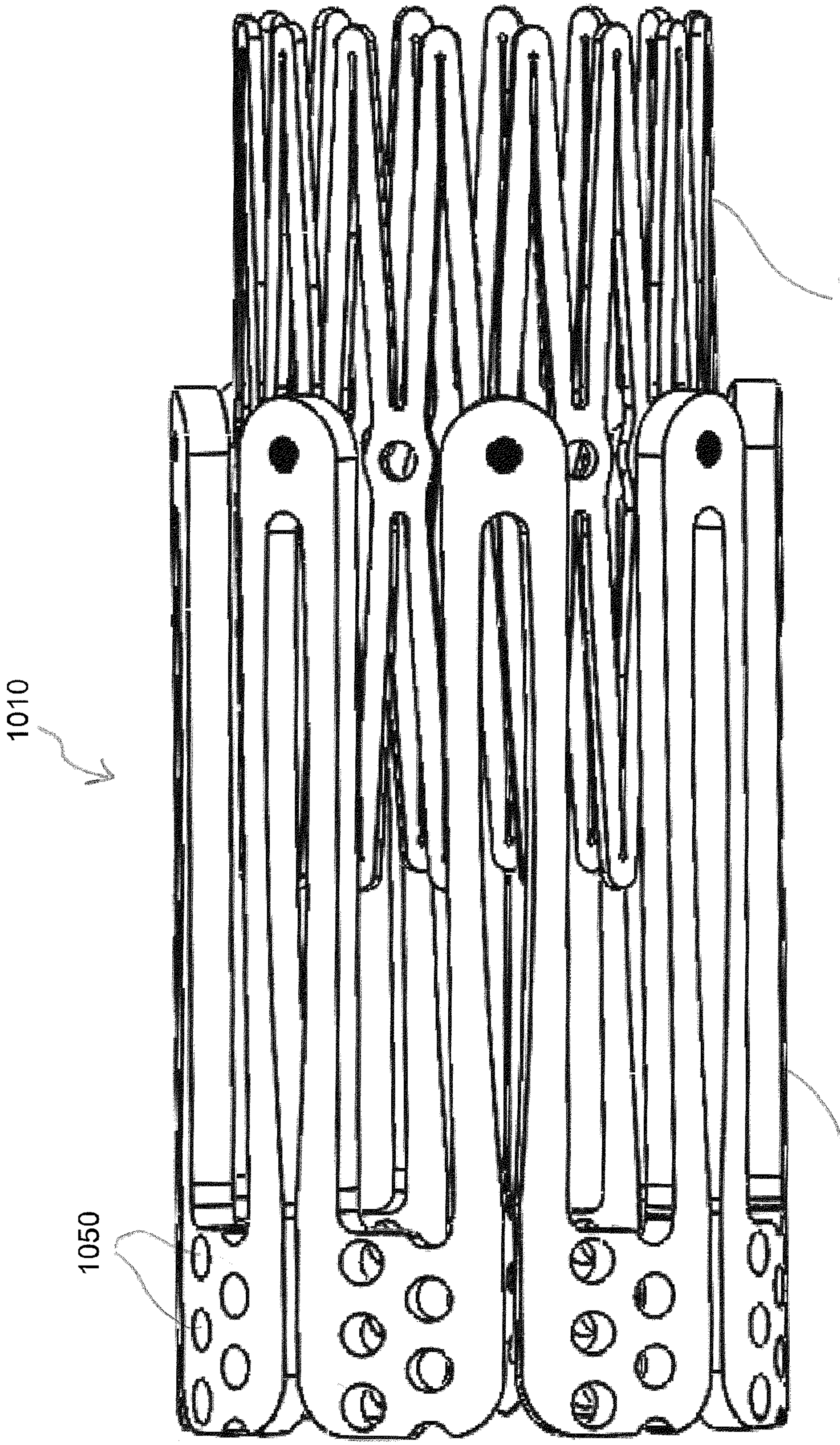


FIG. 11

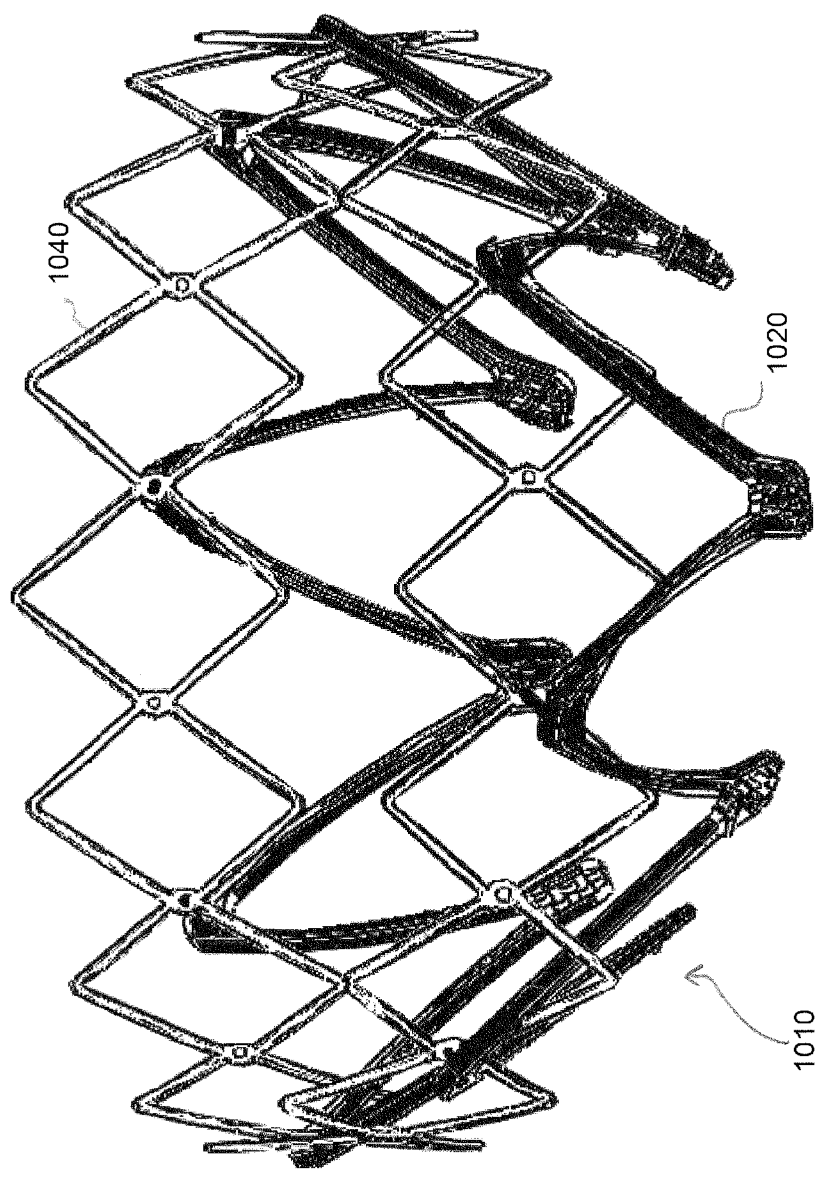


FIG. 12

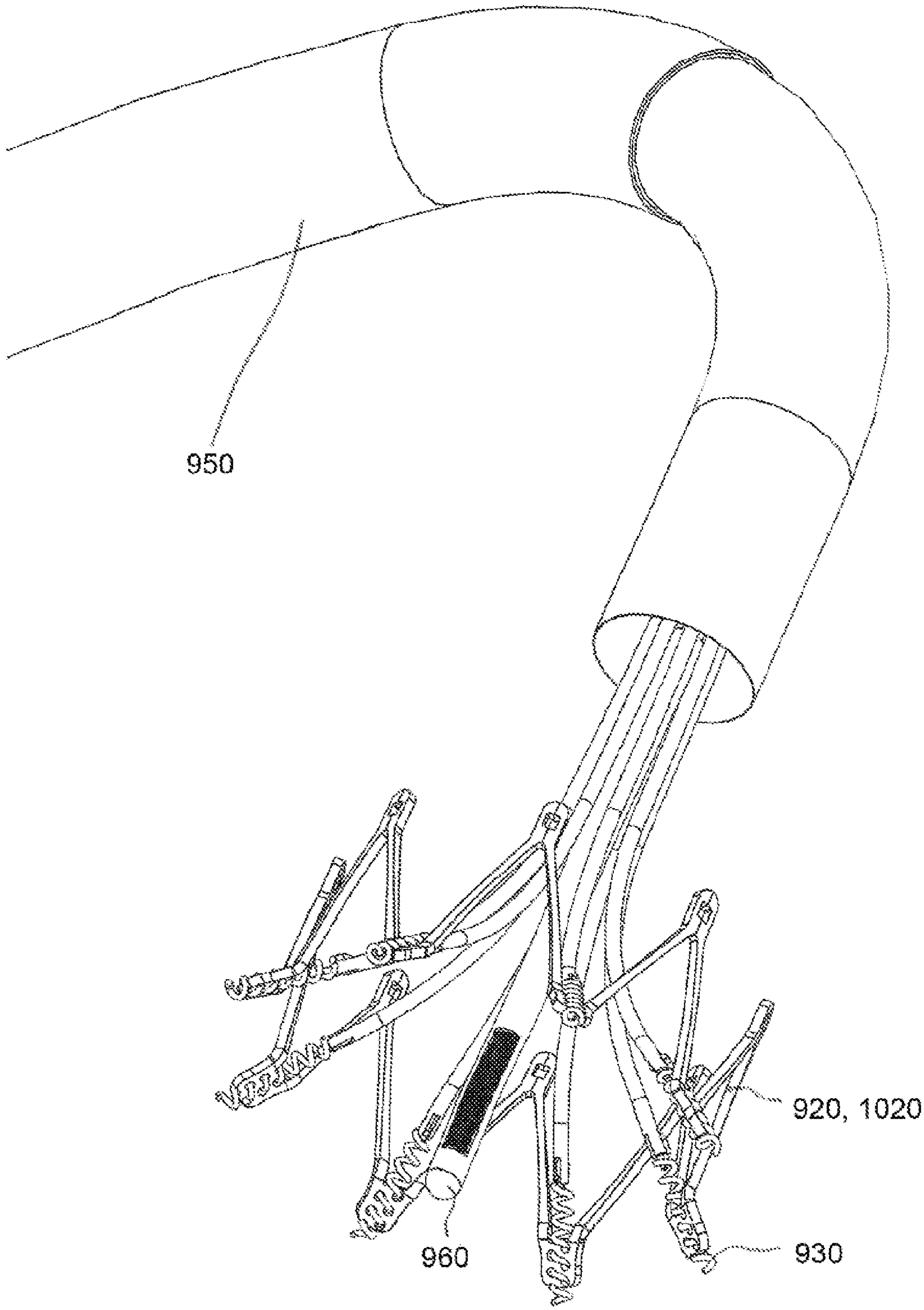


FIG 13

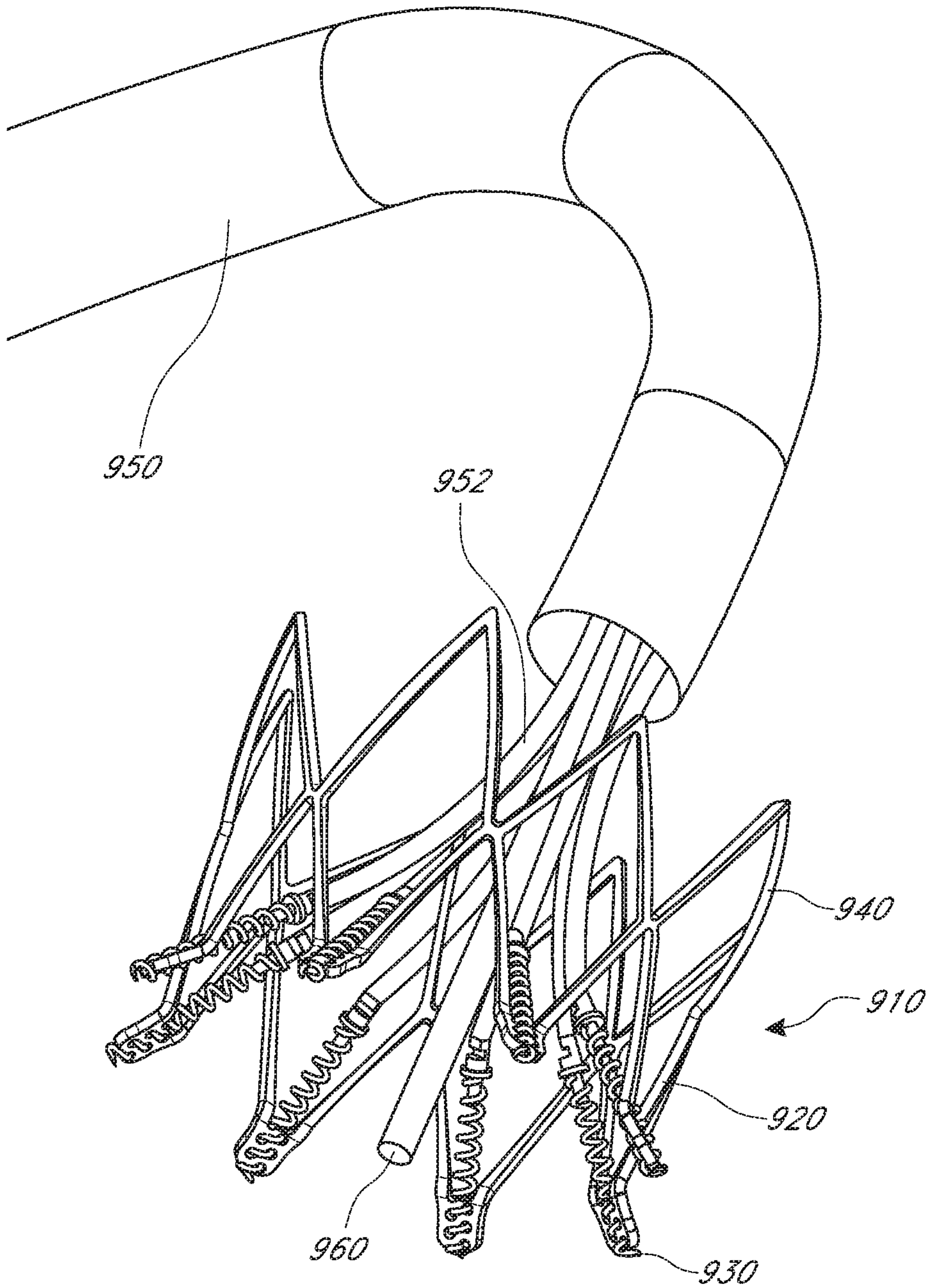


FIG. 14

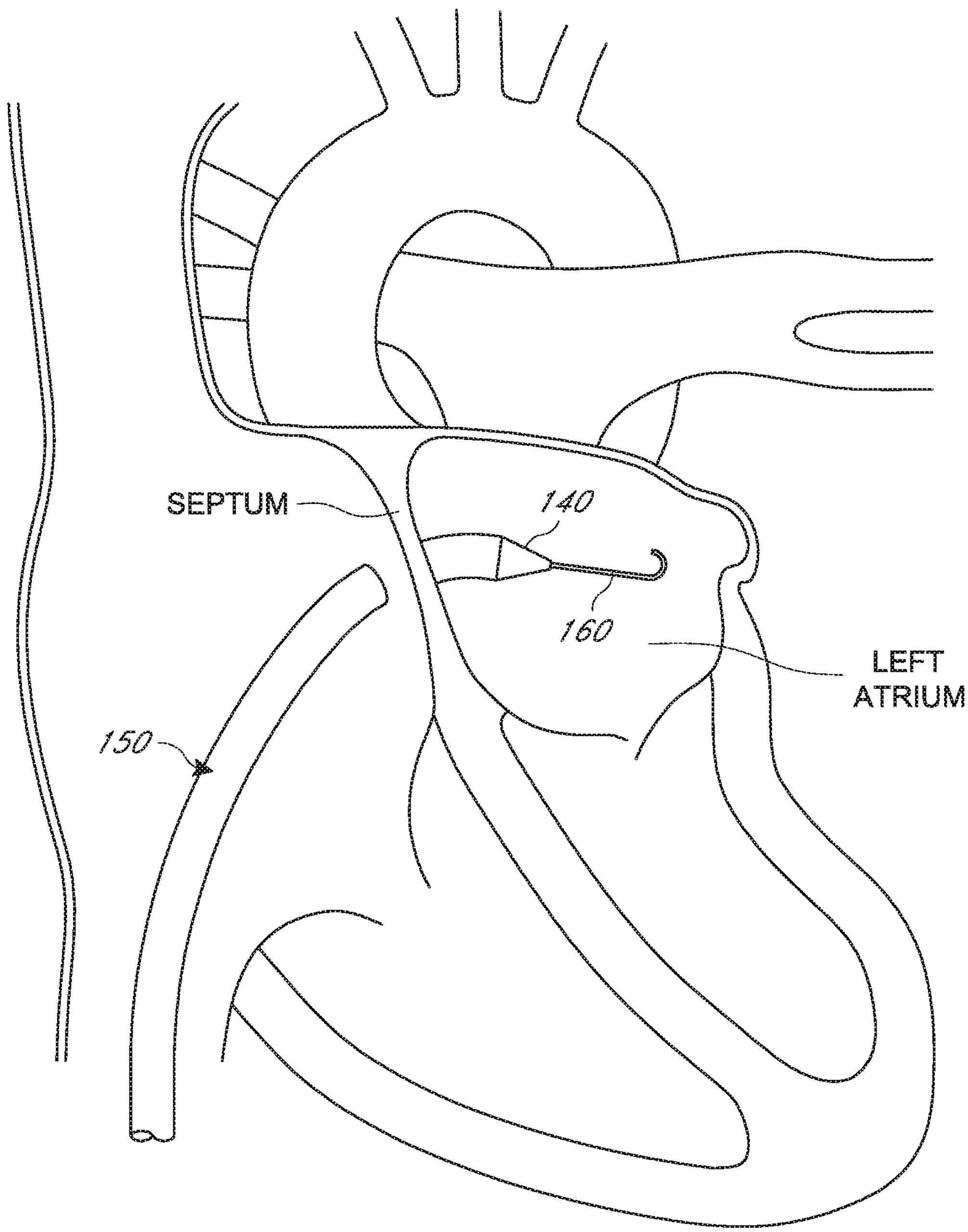


FIG. 15A

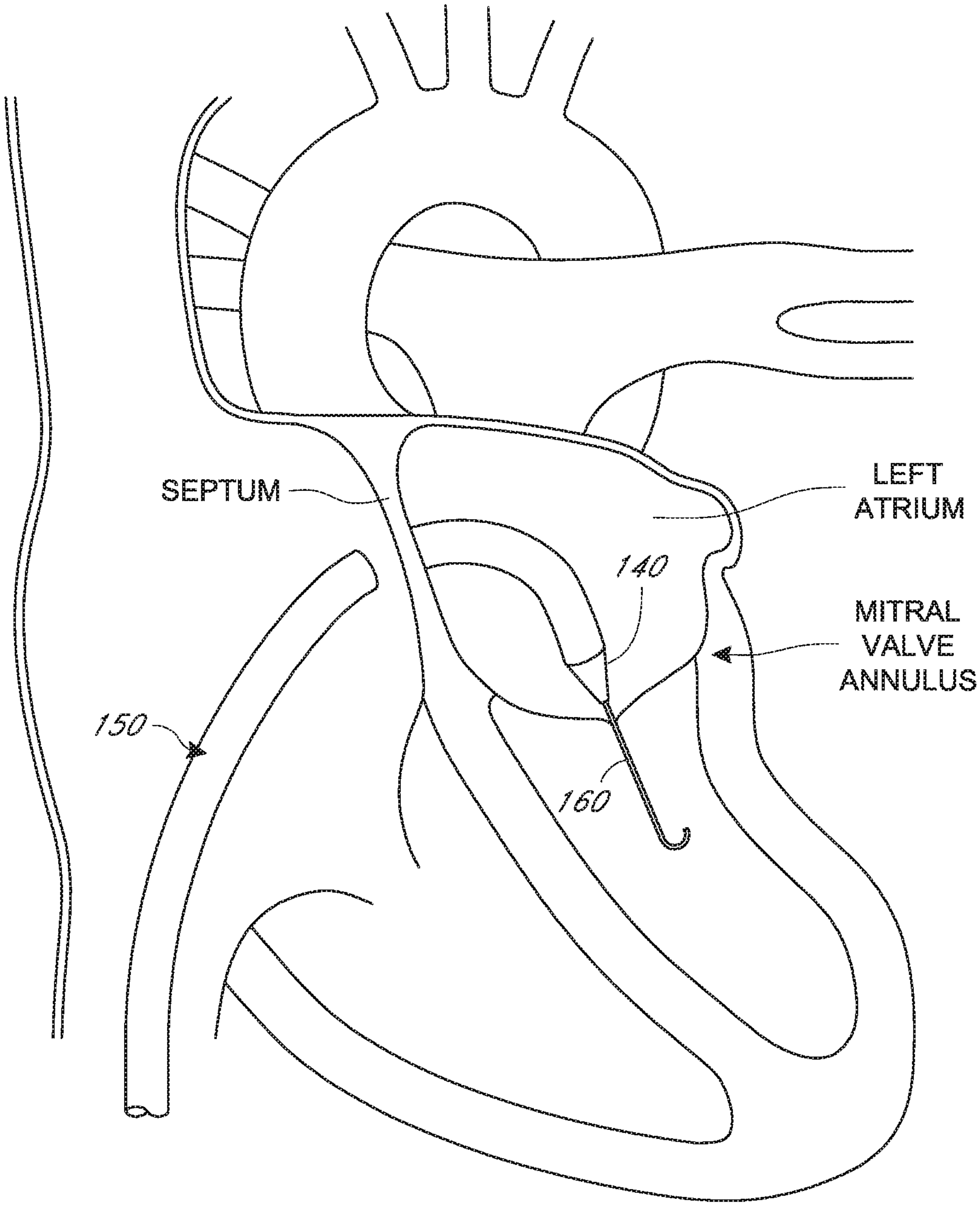


FIG. 15B

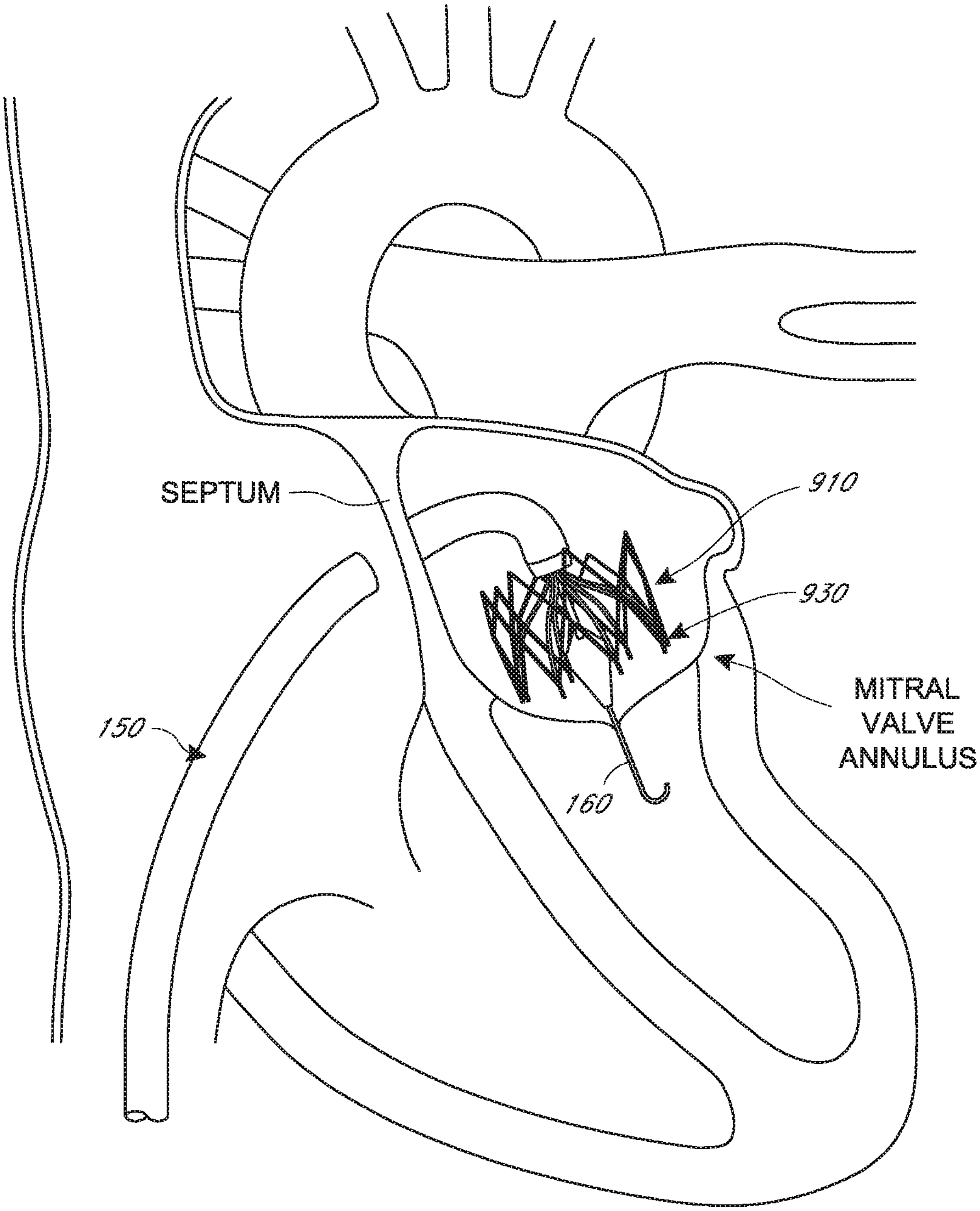


FIG. 15C

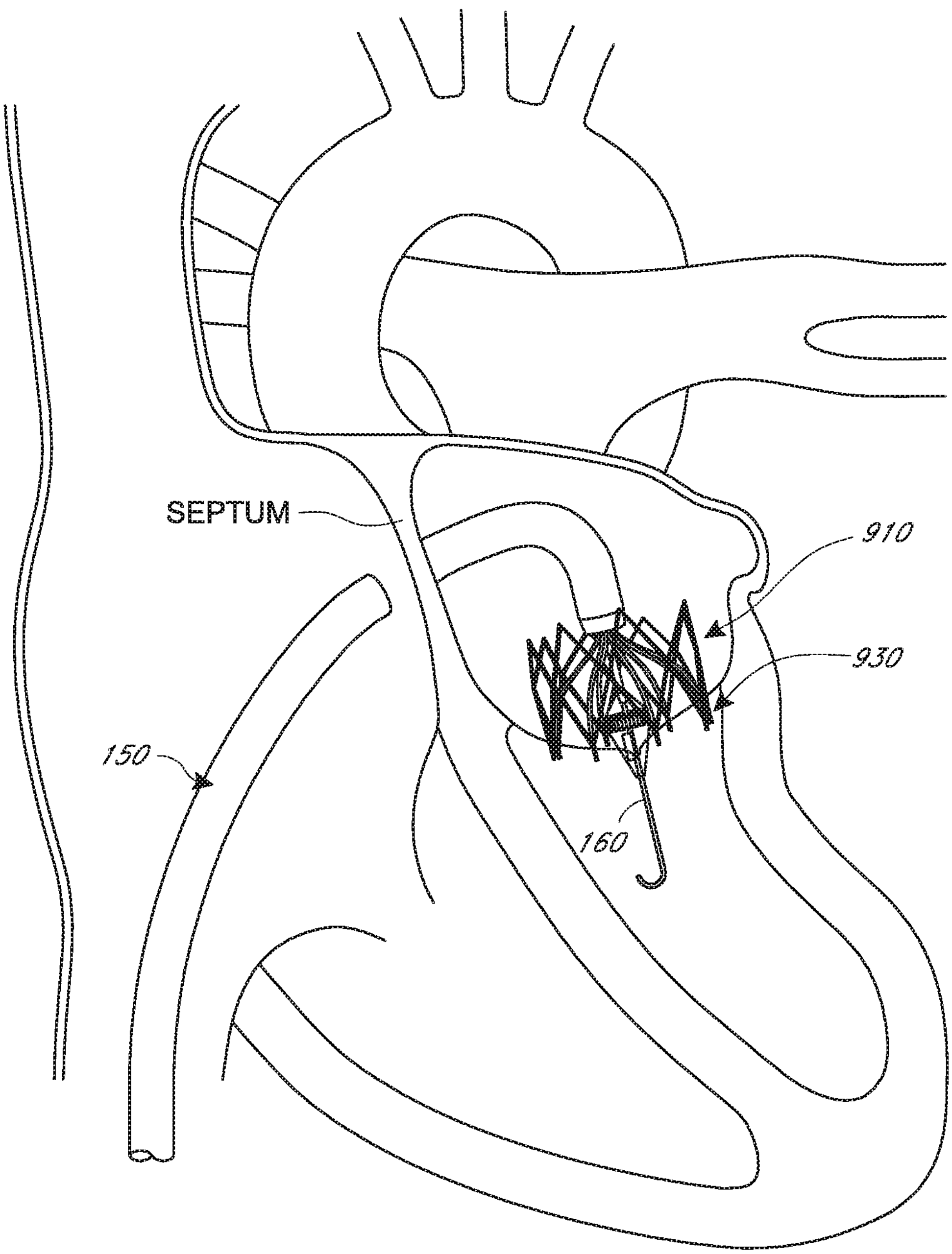


FIG. 15D

MITRAL VALVE INVERSION PROSTHESES

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of Ser. No. 15/423,374, filed Feb. 2, 2017, which claims the benefit of priority to U.S. Provisional Application No. 62/291,347, filed on Feb. 4, 2016, and also which is a Continuation-in-Part application of U.S. application Ser. No. 14/427,909, filed on Mar. 12, 2015, which is a U.S. National Phase Application of PCT International Application No. PCT/US2013/059751, filed on Sep. 13, 2013, designating the United States of America and published in the English language, which is an International Application of and claims the benefit of priority to U.S. Provisional Application No. 61/700,989, filed on Sep. 14, 2012. Each of the above-referenced applications are hereby expressly incorporated by reference in their entireties for all purposes and form a part of this specification. Any and all priority claims identified in the Application Data Sheet, or any correction thereto, are hereby incorporated by reference under 37 C.F.R. § 1.57.

BACKGROUND

A. Field

This disclosure relates generally to cardiac treatment devices and techniques, and in particular, to methods and devices for repair of mitral valve defects such as mitral valve regurgitation.

B. Background of Related Art

The mitral valve is one of four heart valves that direct blood through the two sides of the heart. The mitral valve itself consists of two leaflets, an anterior leaflet and a posterior leaflet, each of which are passive in that the leaflets open and close in response to pressure placed on the leaflets by the pumping of the heart.

Among the problems that can develop or occur with respect to the mitral valve is mitral valve regurgitation (MR), in which the mitral valve leaflets become unable to close properly, thus causing leakage of the mitral valve. Severe mitral regurgitation is a serious problem that, if left untreated, can adversely affect cardiac function and thus compromise a patient's quality of life and life span.

Currently, mitral regurgitation is diagnosed by many indicators, and the mechanism of mitral regurgitation can be accurately visualized by trans-esophageal echocardiography or fluoroscopy with dye injection. The most prevalent and widely accepted current technique to correct mitral regurgitation is to repair the mitral valve via open-heart surgery while a patient's heart is stopped and the patient is on cardiopulmonary bypass, a highly invasive procedure that has inherent risks.

SUMMARY

In one aspect, a method is described comprising inserting an implant proximate a mitral valve, the implant comprising a tubular body and a plurality of piercing members, the tubular body comprising an upper (i.e. proximal) diameter and a lower (i.e. distal) diameter. The method also includes engaging tissue proximate the mitral valve by the plurality of piercing members and transitioning the tubular body from a first structural configuration to a second structural configuration by application of an expansive force to the tubular body proximate the upper diameter, the first structural configuration having the upper diameter smaller than the lower diameter and the second structural configuration having the upper diameter larger than the lower diameter.

In another aspect, an implant is described comprising a tubular body comprising an upper diameter and a lower diameter, the tubular body having a first structural configuration in which the upper diameter is smaller than the lower diameter and a second structural configuration in which the upper diameter is larger than the lower diameter, the tubular body configured to transition from the first structural configuration to the second structural configuration by application of an expansive force to the tubular body proximate the upper diameter. The implant also comprises a plurality of piercing members connected to the tubular body and proximate the lower diameter to engage tissue proximate a mitral valve.

In another aspect, a system is described comprising a guide wire, a sheath over the guide wire, and an implant for delivery to a body by traveling through the sheath and along the guide wire. The implant comprises a tubular body comprising an upper diameter and a lower diameter, the tubular body having a first structural configuration in which the upper diameter is smaller than the lower diameter and a second structural configuration in which the upper diameter is larger than the lower diameter, the tubular body configured to transition from the first structural configuration to the second structural configuration by application of an expansive force to the tubular body proximate the upper diameter. The implant also comprises a plurality of barbs connected to the tubular body and proximate the lower diameter to penetrate tissue proximate a mitral valve.

In another aspect, a delivery system for delivering an implant within the heart for reducing the size of a heart valve annulus is described. The delivery system comprises a plurality of rotatable drivers and the implant. The plurality of rotatable drivers is configured to extend through one or more lumens of the delivery system. The implant is configured for delivery within the heart by traveling through the one or more lumens of the delivery system. The implant comprises a tubular body and a plurality of helical anchors. The tubular body comprises a frame defining a proximal diameter and a distal diameter. The tubular body has a first structural configuration in which the proximal diameter is smaller than the distal diameter and a second structural configuration in which the proximal diameter is larger than the distal diameter. The plurality of helical anchors are connected to the tubular body proximate the distal diameter of the frame. The plurality of helical anchors are configured to be rotated by the rotatable driver to advance the plurality of helical anchors distally relative to the frame and penetrate the heart valve annulus.

In some embodiments of the delivery system, the implant may further comprise a series of distal apices and a series of holes. The series of distal apices may be formed by the frame proximate the distal diameter. The series of holes may be in each of the distal apices and are sized and spaced to receive therethrough a corresponding helical anchor for rotational engagement of the distal apex by the corresponding helical anchor. The plurality of rotatable drivers and the implant may be configured for transcatheter delivery of the implant to the heart. The delivery system may further comprise a delivery catheter comprising the one or more lumens of the delivery system. A distal end of the delivery catheter may be configured to advance through an opening in the femoral vein, through the femoral vein and into the right atrium of

the heart, and through the septum of the heart into the left atrium. The delivery system may further comprise a location ring configured to be located on a side of the heart valve opposite the implant and to couple with the implant. The location ring may be separate from the implant and configured to be located on a side of the heart valve opposite the implant to assist in positioning the implant. The location ring may be configured to be removed from the heart after the implant is positioned and the plurality of helical anchors penetrate the heart valve annulus. The delivery system may comprise one lumen configured to receive therethrough an intracardiac echo catheter for visualizing a position of the implant relative to the mitral valve annulus. The delivery system may further comprise the intracardiac echo catheter. The implant may further comprise an expandable tubular member coupled with a proximal end of the frame and configured to expand to increase the proximal diameter of the frame. The expandable tubular member may be integral with the frame.

In another aspect, an implant for reducing the size of a heart valve annulus is described. The implant comprises a tubular body and a plurality of helical anchors. The tubular body comprises a frame defining a proximal diameter and a distal diameter. The tubular body has a first structural configuration in which the proximal diameter is smaller than the distal diameter and a second structural configuration in which the proximal diameter is larger than the distal diameter. The plurality of helical anchors are connected to the tubular body proximate the distal diameter of the frame. Each of the plurality of helical anchors is configured to be rotated by a plurality of rotatable drivers through a series of holes in lower apices of the frame to advance the plurality of helical anchors distally relative to the frame and penetrate the heart valve annulus.

In some embodiments, the implant further comprises an expandable tubular member proximate a proximal end of the frame, wherein when force is applied to the expandable member, the expandable member expands and engages the proximal end of the frame causing the frame to invert from the first structural configuration to the second structural configuration. The expandable tubular member may be integral with the proximal end of the frame. The expandable tubular member may be a stent-like member positioned internally of the frame proximate the proximal diameter of the frame. The implant may be configured to be contracted to a delivery configuration for transcatheter delivery of the implant to the heart by a delivery system. The implant may further comprise an expandable tubular member coupled with a proximal end of the frame, wherein contracting the expandable tubular member for transcatheter delivery causes the proximal diameter of the frame to decrease relative to an unconstrained state, which causes the distal diameter of the frame to increase relative to the unconstrained state such that the proximal and distal diameters of the frame are approximately the same when delivered. The implant may further comprise angled segments of the frame forming distal apices of the frame proximate the distal diameter, and the series of holes in each of the distal apices may be sized and spaced to receive therethrough a corresponding helical anchor for rotational engagement of the distal apex by the corresponding helical anchor. The tubular body may be configured to transition from the first structural configuration to the second structural configuration by application of an expansive force to the tubular body proximate the proximal diameter.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present disclosure and its features and advantages, reference is now made to the following description, taken in conjunction with the accompanying drawings, in which:

FIGS. **1**A-**1**F illustrate an example embodiment of an implant in accordance with the present disclosure;

FIGS. **2**A-**2**D illustrate an alternative example embodiment of an implant in accordance with the present disclosure;

FIGS. **3**A-**3**B illustrate a further alternative example embodiment of an implant in accordance with the present disclosure;

FIGS. **4**A-**4**B illustrate an additional example embodiment of an implant in accordance with the present disclosure;

FIG. **5** illustrates examples of delivery routes of an implant, in accordance with the present disclosure;

FIG. **6** illustrates an example embodiment of the present disclosure utilizing vibrations, in accordance with the present disclosure;

FIG. **7** illustrates an alternative example embodiment of the present disclosure utilizing vibrations, in accordance with the present disclosure; and

FIG. **8** illustrates an additional example embodiment of the present disclosure utilizing vibrations, in accordance with the present disclosure.

FIGS. **9**A-**9**B are perspective views of other embodiments of implants having rotatable helical anchors for securing the implants to a valve annulus.

FIG. **10**-**12** are perspective views of another embodiment of an implant, having an expandable tubular element, and configured to be secured to a valve annulus with helical anchors.

FIG. **13** is a perspective view of an embodiment of a delivery system shown delivering an embodiment of the implant of FIGS. **10**-**12**.

FIG. **14** is a perspective view of an embodiment of a delivery system shown delivering the implant of FIG. **9**A.

FIGS. **15**A-**15**D are sequential views of an embodiment of a transcatheter delivery system for delivering the implant of FIG. **9**A showing an embodiment of a method for the delivery, positioning and anchoring of the implant.

DETAILED DESCRIPTION

The present disclosure relates to an implant including a tubular body and piercing members for reshaping a mitral valve suffering from mitral regurgitation. The implant may include two or more structural configurations. In a first structural configuration, an upper, i.e. proximal, diameter (away from the mitral valve) may be smaller than a lower, i.e. distal, diameter (proximate the mitral valve). In this first structural configuration, the piercing members of the implant may engage the tissue proximate the mitral valve, for example, the mitral valve annulus. The implant may then be transitioned from the first structural configuration to a second structural configuration in which the size of the upper diameter is larger than the lower diameter. This may be facilitated by an expansive force causing the upper diameter to expand, in turn causing the lower diameter to contract. As the lower diameter contracts, the penetrating members engaged with the tissue proximate the mitral valve may cause the mitral valve to also contract to a smaller diameter. This may allow the valve leaflets to close properly, addressing mitral regurgitation.

FIGS. **1**A-F illustrate one embodiment of an implant. For example, as shown in FIG. **1**A, in some embodiments, repair of a mitral valve may be achieved by a catheter system and catheterization procedure, wherein a catheter may be configured for percutaneous access to the mitral valve through the left ventricle. Access may be granted to the left ventricle through the apex of the heart where an incision may be made to insert a dilator and sheath **150** for access of a repair catheter **140**. Sheath **150** may measure about six French to about thirty French and a closure device may be used in conjunction with the entry of this access catheter **140**.

In one embodiment of the present disclosure, catheter **140** may include an extendable guide wire assembly **160**, which may guide the system into position. Guide wire **160** may measure between 0.010 inches and 0.038 inches in diameter, and may be 0.035 inches in diameter. Catheter **140** or sheath **150** when accessed through the apex of the heart may measure about twenty to thirty centimeters in length.

As shown in FIG. **1**B, once access has been achieved, a delivery system may be introduced through sheath **150** along guide wire **160** with implant **110** for reducing the diameter of the mitral valve annulus. Catheter **140** may deliver implant **110** to resize the mitral valve to reduce the mitral valve cross sectional area or move the posterior leaflet back into position limiting or reducing mitral valve regurgitation.

Implant **110** may include a tubular body with portions of the tube removed similar to a stent structure where a portion of the material may be removed via laser cutting or other means to selectively cut portions of the tube away forming a radially-expandable tubular body. Implant **110** may be introduced in a collapsed structural configuration. This collapsed structural configuration may allow implant **110** to fit within sheath **150** to allow for a percutaneous procedure rather than an open-heart procedure. As shown in FIG. **1**B, once implant **110** arrives in the left atrium, implant **110** may be expanded to a larger first structural configuration to engage tissue proximate the mitral valve, for example, the mitral valve annulus. In one embodiment, implant **110** may have a tubular shape with a free diameter of about twenty five to about thirty five millimeters in diameter, a height of about ten to about thirty millimeters, and a wall thickness of between about 0.005 inches and about 0.040 inches. Implant **110** may be constructed of a metallic material such as stainless steel, MP35N alloy, Nitinol or other implantable material.

In some embodiments, implant **110** may be tapered such that one end may be larger in diameter than the other end, appearing generally frustoconical in shape. The diameters of the ends may be approximately twenty five millimeters on the smaller end and approximately thirty five millimeters on the larger end. Implant **110** may also be non-circular where a portion of the implant may be elliptical or include a radial portion that is flat. This flat portion may be oriented toward the aortic valve and the circular portion may be positioned toward the posterior leaflet. To facilitate discussion of implant **110**, an upper portion and lower portion may be described. The lower portion may refer to the end of implant **110** proximate mitral valve **170** while the upper portion may refer to the end of implant **110** free in the left atrium.

Implant **110** may include piercing members **115** proximate the lower portion of implant **110** proximate mitral valve **170** to engage with tissue proximate mitral valve **170**, for example, the mitral valve annulus. Piercing members **115** may include barbs or hooks similar to fish hook barbs or other similar feature to resist withdrawal from tissue once pierced. Piercing members **115**, barbs or hooks of the piercing members **115**, or any combination thereof may pierce the tissue to engage with the tissue. Piercing members **115** may include a singular barb or hook, or a plurality of barbs or hooks per piercing member **115**. Piercing members **115** may be immediately exposed or covered for delivery. They may number from one to fifty and may have a length of about four to twenty millimeters in length. They may have the same wall thickness as a wall of the tubular body of implant **110** or may differ with an increased or decreased thickness or taper in either direction to allow for mechanical integrity.

Piercing members **115** of implant **110** may be integral or attached to implant **110** as a secondary component glued, welded, or attached as an ancillary part. Piercing members **115** may also be laser cut into implant **110**, and therefore attached to implant **110**. The barbs or hooks may be fatigue resistant from fracture or separation from piercing members **115**. For example, the barbs or hooks may have additional strength or wall thickness at the connection to piercing members **115**. The barbs or hooks may also be attached with a hinged attachment allowing motion relative to the heart, but not longitudinally where the barbs or hooks may separate from piercing member **115**.

The barbs or hooks of piercing member **115** may be active or passive meaning that the barbs or hooks may be activated with heat to bend or expose or mechanically formed through an external force to bend or expose. For example, each barb or hook may be sheathed inside a tube and removal of this tube may allow the barb or hook to be activated by, for example, body heat or some other activation factor, such that the barb or hook is exposed so as to engage the surrounding tissue. In a passive configuration, the barbs or hooks may be static in nature and either always exposed or exposed as soon as a covering is removed. The barbs or hooks may be hidden until deployment limiting the exposure during delivery and positioning and only exposed once positioning is finalized. The exposure may be completed as individual barbs or as multiples of barbs. In some embodiments, the covering is thus only a temporary covering.

As shown in FIG. **1**B, in some embodiments, implant **110** may be positioned at the annulus of mitral valve **170** where the mitral valve hinge meets the left ventricle and the left atrium meets mitral valve **170**. Positioning implant **110** at this location may be facilitated using a location ring **120**. For example, location ring **120** may be positioned within the left ventricle, under mitral valve **170**. A catheter to deliver location ring **120** may be placed in the left ventricle via the same access point through sheath **150**. In some embodiments, a catheter **130** may extend through the aorta to deliver and/or remove the location ring **120**. The catheter **130** as shown may extend through the aorta and through the aortic valve, and enter the left ventricle. In some embodiments, the location ring **120** may be delivered and/or removed from the apical entry point, as mentioned, or from trans-aortic entry via a femoral entry. In some embodiments, location ring **120** may comprise a metallic ring or coiled section, which may be viewed via fluoroscopy or echo guidance to confirm the location of location ring **120**. This may allow confirmation of a positive location for implant **110** to be located with respect to the mitral valve annulus. In addition to the use of a location ring, other methods for determining a desired location to attach implant **110** may could include echo guidance, CT, fluoroscopy or MRI other imaging techniques to highlight the mitral valve hinge.

As shown in FIG. **1**C, while in a first expanded structural configuration, and once a proper position has been achieved, implant **110** may have a downward force "A" applied to cause piercing members **115** to engage with and/or pierce the mitral valve annulus. This force may be applied by the delivery system itself, or may be applied by a secondary catheter that may be introduced for engaging piercing members **115** with the tissue proximate mitral valve **170**.

As shown in FIG. **1**D, the location ring **120** may be used to locate the relative position of the implant **110** after anchoring the implant **110** to the annulus. For example, the location ring **120** may comprise a metallic ring or coiled section, which may be viewed via fluoroscopy or echo guidance to confirm the location of location ring **120** and implant **110**. After confirmation of acceptable placement of the implant **110**, or after inversion of the implant **110** as described below, the location ring **120** may then be removed. Thus, the location ring **120** may be temporary. The location ring **120** may thus be separate from the implant **110** and configured to be located on a side of the heart valve opposite the implant **110** to assist in positioning the implant **110**. The location ring **120** may be configured to be removed from the heart after the implant **110** is positioned and the plurality of helical anchors penetrate the heart valve annulus. The location ring **120** may be removed by the same delivery system by which it was inserted, for example the delivery system shown in FIGS. **1**A-**1**F, the catheter **130**, etc.

In some embodiments, location ring **120** may also act as an anchor for implant **110**. In such an embodiment, implant **110** above mitral valve **170** (i.e. in the left atrium side of mitral valve **170**) may attach to location ring **120** below mitral valve **170** (i.e. in the left ventricle side of mitral valve **170**). For example, the hooks or barbs of piercing members **115** may engage with location ring **120**. This may be accomplished by a through suture, a barbed means, wrapping or clipping location ring **120** to implant **110**. Magnetic forces may also hold location ring **120** and implant **110** together either temporarily or permanently. Alternatively, the hooks or barbs may also be attached to some other separate implant below mitral valve **170** in the left ventricle. This may be a wire, ring, or tee anchor to secure implant **110** to via wires, threads or mechanical means to attach through the tissue median. For convenience, this implant below mitral valve **170** may be referred to as location ring **120**, even if not used in locating implant **110** proximate mitral valve **170**.

In some embodiments, the shape of location ring **120** may be a circular cross section measuring about 0.010 inches to about 0.090 inches in diameter and may encircle the mitral annulus. The shape may also be non-circular, oval, biased to one axis or multi-axis to accommodate the multi-plane shape of mitral valve **170**, which is more saddle shaped. It may also have a variable stiffness in different sections to accommodate tighter bends in the placement of location ring **120**. Location ring **120** and or a delivery catheter may also be steerable to navigate the area under mitral valve **170** for ease of placement. Utilizing push pull wires to compress or load portions of the catheter or location ring **120** to predictably bend and orient the catheter or location ring **120** may allow a user to access difficult anatomical features en route to and around mitral valve **170**.

As shown in FIG. **1**E, once piercing members **115** have engaged the tissue proximate mitral valve **170**, for example, the mitral valve annulus, an expansive force "B" may be applied to the upper portion of implant **110**. By applying expansive force "B" to implant **110**, a reactive reducing force "C" may also be produced at the lower portion of implant **110**. As the diameter of the lower portion is decreased from reactive reducing force "C," the diameter of mitral valve **170** is also reduced due to the attachment of implant **110** to the tissue around mitral valve **170**. For example, once a sufficient reducing force "C" has been generated to reshape mitral valve **170** to a desired size, implant **110** may be left in a final position in which the size change of mitral valve **170** may be maintained. This may be a second structural configuration.

As shown in FIG. **1**F, in some embodiments, piercing members **115** may engage the tissue proximate mitral valve **170** but not engage location ring **120**. In such an embodiment, the barbs or hooks of piercing members **115** may bind, engage with, and/or resist withdrawal from tissue proximate mitral valve **170** in a manner sufficient to keep implant **110** attached to the tissue proximate mitral valve **170**. Additionally, the binding, engaging, and/or resisting withdrawal may be sufficient to decrease the surface area of mitral valve **170** as expansive force "B" and reactive reducing force "C" are applied. In such an embodiment, location ring **120** may or may not be used to facilitate placing implant **110** at a positive location proximate mitral valve **170**. In some embodiments, as described, the location ring **120** may not couple with the implant **110** but may be used to facilitate positioning of the implant **110**, such as by temporarily positioning the location ring **120**, etc. A positive location for implant **110** may be one in which implant **110** is able to engage tissue proximate mitral valve **170** without impairing the function of mitral valve **170** and further implant **110** may be used to decrease the surface area of mitral valve **170** as expansive force "B" and reactive reducing force "C" are applied.

FIGS. **2**A-**2**D illustrate an example of implant **110** in accordance with the present disclosure. As shown in FIG. **2**A, implant **110** may be made of a metal and cut to form a mesh, a cage, or series of repeating units to allow variations in diameter. For example, implant **110** may include a tubular body of repeating squares, diamonds, hexagons, or any other shape allowing a variation in diameter of implant **110**. In first structural configuration as shown in FIG. **2**A, implant **110** may have the larger diameter portion initially oriented toward mitral valve **170** (the lower portion with lower diameter **220**) and the smaller diameter may be oriented in the left atrium (the upper portion with upper diameter **210**). The upper portion may be in free space in the left atrium and have a smaller diameter ready to be expanded in this first structural configuration.

The construction of implant **110** may include a tapered laser cut tube expanded to a predetermined diameter with wall thickness approximately 0.005 inches to approximately 0.050 inches and a strut thickness of approximately 0.010 inches to approximately 0.070 inches and an expanded diameter of approximately 1.00 inch. If the implant is tapered, the large diameter may measure about thirty five millimeters in diameter and the smaller diameter may measure about twenty five millimeters in diameter. In the first structural configuration, the lower portion (i.e. the larger diameter section) may have penetrating members **115** to engage the mitral annulus and hold implant **110** in position during annuls reduction and remain as a permanent implant.

As shown in FIG. **2**B, downward force "A" may be applied to implant **110**. In some embodiments, piercing members **115**A-H may be driven to engage the tissue one at a time. For example, a linear force may drive the hooks or barbs of piercing member **115**A into the tissue by pushing at the top of implant **110** above piercing member **115**A, thus transmitting a force through to the piercing member **115**A, driving it into the tissue. The delivery system or catheter applying the force may then be rotated and actuated again to engage another piercing member **115**, for example adjacent piercing member **115**B. Once piercing member **115**B has been engaged with the tissue, this may be repeated until all piercing members **115** have been engaged with the tissue. Alternatively, in some embodiments, force "A" may be sufficient to engage multiple piercing members **115** at once, rather than engaging only a single piercing member **115** at a time. In some embodiments, all of piercing members **115** may be engaged at once.

As shown in FIG. **2**C, implant **110** may be in a first structural configuration in which upper diameter **210** may be smaller than lower diameter **220**. An expansive force "B" may be applied to the upper portion of implant **110**. As the expansive force "B" is applied such that the upper diameter **210** is increased, the lower diameter **220** may be decreased due to a reactive reductive force "C" which is generated. A wall of the tubular body of implant **110** may act as a beam in deflection where the upper portion of implant **110**, when deflected (e.g. expanded), may cause the lower portion of implant **110** to bend (e.g. contract). This may facilitate the transition from this first structural configuration to a second structural configuration. The lower diameter **220** may be proximate piercing members **115**, which are engaged with the mitral valve annulus. Thus, as lower diameter **220** becomes smaller, the diameter of mitral valve **170** becomes smaller. The expansive force "B" may be applied via balloon dilation, mechanical expansion or other means to increase upper diameter **210**, thus reducing lower diameter **220**. This may effectively invert implant **110**'s dimensions about axis **200**, which may be referred to as an axis of inversion or axis of reflection. In some embodiments, the diameter of implant **110** at axis **200** may remain approximately uniform in a first structural configuration, transitioning between structural configurations, and a second structural configuration. As shown in FIG. **2**D, the application of expansive force "B" and thus reactive reducing force "C" may result in implant **110** with upper diameter **210** having a larger length and lower diameter **220** having a shorter length. This may in turn reduce barb-engaged mitral valve **170** to a smaller annulus cross-sectional area, lessening the mitral regurgitation. The structural configuration shown in FIG. **2**B may be the second structural configuration of implant **110** in which mitral valve **170** has been reduced in annulus cross-sectional area. Additionally, this second structural configuration may be a final structural configuration that may maintain the size change of mitral valve **170**.

As shown in FIGS. **3**A and **3**B, an alternative method for applying an expansive force to implant **310** may be the deployment of a ring **320** within implant **310**. FIG. **3**A illustrates implant **310** in a first structural configuration and FIG. **3**B illustrates implant **310** in a second structural configuration. The ring **320** may be formed of a shape memory material, such as nitinol. The ring **320** may be collapsed into a delivery catheter for delivery therethrough to the heart and ejected into or around the implant **310**. In some embodiment, one or more releasable tethers may be attached to the ring **320**. The releasable tethers may be pulled on to move the ring **320** and to release the tethers from the ring **320** after the ring **320** is in the desired location.

In some embodiments, a fixed ring **320** may be utilized. Fixed ring **320** may be moved vertically to expand the upper portion to increase upper, i.e. proximal, diameter **330**, thus causing the lower portion to reduce lower, i.e. distal, diameter **340** along with the engaged tissue and mitral valve. For example, upward force "D" may be applied to ring **320**. However, because of the frustoconical shape of implant **310**, the upward force "D" may be translated to an expansive lateral force causing an increase in upper diameter **330**. Ring **320** may lock into implant **310** by an interference fit or a mechanical stop built in ring **320** or implant **310**, and may maintain implant **310** in the second structural configuration. In some embodiments, the fixed ring **320** may have a smaller diameter and initially be located at or near the upper diameter **330**, thus restraining the upper diameter **330** and causing and/or maintaining the first structural configuration of the implant **310** shown in FIG. **3**A. The fixed ring **320** may then be moved vertically downward as oriented toward the lower diameter **340**, thereby allowing the upper diameter **330** to expand and increase in size and causing the lower diameter **340** to contract and reduce in size. The fixed ring **320** may then be located at or near the lower diameter **340** to cause and/or maintain the second structural configuration of the implant **310** shown in FIG. **3**B.

Alternatively, an expandable ring **320** may be used rather than a fixed ring. Expandable ring **320** may be positioned within implant **310** and may be delivered and expanded by a catheter, for example using hydraulic or mechanical force to expand ring **320**. Ring **320** may be introduced into implant **310**'s inner diameter where ring **320** may be tilted to allow for manipulation or positioning. Alternatively, ring **320** may be placed at a defined vertical position in implant **310** and ring **320** may be expanded, for example with mechanical or hydraulic force or an extension of the radial dimension. Ring **320** may also serve as a locking mechanism for implant **310** once the second structural configuration or the final position has been reached. The expansion and/or locking of ring **320** may be reversible in nature, thus undoing the expansion of the upper portion. Ring **320** may lock into implant **310**, for example by an interference fit or a mechanical stop built in ring **320** and/or implant **310**.

FIGS. **4**A and **4**B illustrate an additional embodiment of an implant **410** for reshaping mitral valve **170**. FIG. **4**A illustrates implant **410** in a first structural configuration and FIG. **4**B illustrates implant **410** in a second structural configuration. As shown in FIG. **4**A, in some embodiments, implant **410** may include one or more support beams **420** (for example, support beams **420**A and **420**B). Support beams **420** may facilitate the transition of expansive force "B" to the reductive force "C." For example, support beam **420** may operate as a beam in deflection about axis **450**. Thus, as expansive force "B" is applied to the upper portion of implant **410**, beams **420**A and **420**B may act as levers with axis **450** as the fulcrum or point of rotation, causing reductive force "C" to reduce lower diameter **440**. As expansive force "B" is applied to increase upper diameter **430** and decrease lower diameter **440**, implant **410** may transition from a first structural configuration shown in FIG. **4**A to a second structural configuration shown in FIG. **4**B. As described above, this may reduce the cross-sectional area of mitral valve **170**.

Support beams **420**A and **420**B may be integrally formed with implant **410**, for example, as a thicker portion of a wall of the tubular body of implant **410**, or a specific alignment of repeating units or elements of the structure of the wall of the tubular body. Alternatively, support beams **420**A and **420**B may be an additional support component added to implant **410**. For example, they may be glued, welded, or otherwise permanently affixed to implant **410**.

As shown in FIG. **5**, in addition to access to mitral valve **170** through the apex of the heart as shown by **510**, access to mitral valve **170** may also be gained via the femoral artery as shown by **530**, or via the femoral artery and through the aortic valve (for example, as described above with respect to delivery/removal of the location ring **120** through the aortic valve) or through the venous system and then via trans-septal puncture directly into the left atrium as shown by **520**. When accessed via the femoral artery or trans-septally, a delivery catheter may measure about ninety to one hundred and fifty centimeters in length. The end of the catheter may be deflectable via deflection wires creating tension of bias to allow adjustments due to anatomical variations.

As shown in FIG. **6**, vibration may be applied directly to penetrating members **115** to facilitate the barbs or hooks and/or penetrating members **115** penetrating the tissue. Low frequency vibration, ultrasonic, or Radio Frequency energy may allow a lower insertion force compared to the barb or hook's and/or penetrating members' normal penetration force. Coupling this energy source to implant **110** may allow transmission of small vibrations **620** to the tip of each barb or hook and/or penetrating member **115**. Alternatively, each barb or hook and/or penetrating member **115** may have its own independent energy source allowing a variable pattern of frequency or energy around implant **110**. Direct tissue contact of the energy element or a coupling to implant **110** may be used but there may be a decrease in efficiency by coupling vibration **620** thereto. The frequency of vibration **620** may be about ten to one hundred Hz (cycles per second) or may be about twenty Hz.

As shown in FIGS. **7** and **8**, to aid in the engagement of the penetrating members **115**, additional energy may be added to vibrate the tissue surrounding or below mitral valve **170**. For example, as shown in FIG. **7**, vibration pads **710**A and **710**B may deliver vibration **620** to the surrounding tissue near the barbs or hooks of penetrating members **115**. Pads **710**A and **710**B may be used to vibrate the tissue near the barb insertion site. Pads **710**A and **710**B may be completely separate from implant **110** or may be connected to the same delivery system. A separate control for linear and radial motion of pads **710**A and **710**B may be provided to control the location to provide precise delivery of vibration **620**.

As shown in FIG. **8**, vibration pads **810**A and **810**B may also be located below mitral valve **170**. This may still provide vibration **620** to facilitate the engagement of barbs or hooks of penetrating members **115** with tissue proximate mitral valve **170**. As with the embodiment of FIG. **7**, vibration pads **810**A and **810**B may be completely separate from implant **110** or may be connected to the same delivery system. A separate control for linear and radial motion of pads **810**A and **810**B may be provided to control the location to provide precise delivery of vibration **620**.

Radio frequency (RF) is a rate of oscillation in the range of about three kHz to three hundred GHz, which corresponds to the frequency of radio waves, and the alternating currents, which carry radio signals. RF usually refers to electrical rather than mechanical oscillations. Below is a chart of common nomenclature for different frequency ranges. The range utilized for barb penetration may be somewhere between ELF and HF as the goal is small vibration and not heating of the tissue. Possible user range selection would allow for different tissue types and densities.

TABLE 1

Frequency	Wavelength	Designation	Abbreviation
3-30 Hz	10^5-10^4 km	Extremely low frequency	ELF
30-300 Hz	10^4-10^3 km	Super low frequency	SLF
300-3000 Hz	10^3-100 km	Ultra low frequency	ULF
3-30 kHz	100-10 km	Very low frequency	VLF
30-300 kHz	10-1 km	Low frequency	LF
300 kHz-3 MHz	1 km-100 m	Medium frequency	MF
3-30 MHz	100-10 m	High frequency	HF
30-300 MHz	10-1 m	Very high frequency	VHF
300 MHz-3 GHz	1 m-10 cm	Ultra high frequency	UHF
3-30 GHz	10-1 cm	Super high frequency	SHF
30-300 GHz	1 cm-1 mm	Extremely high frequency	EHF
300 GHz-3000 GHz	1 mm-0.1 mm	Tremendously high frequency	THF

Vibration to enhance tissue penetration by the anchor may be delivered from a vibration source to tissue adjacent the penetration site, such as by the vibration pads discussed above. The vibration source may be embedded in the pad or other vibration interface at the distal end of an elongate control element such as a wire or tube. Alternatively, the vibration source may be located in a proximal manifold and propagate vibrational energy distally through an elongate wire or tube extending through the catheter body. The vibration source can alternatively be coupled in vibration propagating communication with either the implant frame or with each individual anchor directly, such as through the anchor driver, depending upon desired performance.

FIG. **9**A depicts another embodiment of an implant **910**. The implant **910** may have the same or similar features and/or functionalities as other implants described herein, and vice versa, except as otherwise described. Implant **910** comprises a frame **920**, piercing members or anchors **930**, and may include an expandable member **940**. The frame **920** has a free or unconstrained state or, otherwise stated, nominal configuration as shown in FIG. **9**A. The frame **920** may be made of a nickel titanium alloy, i.e. nitinol, or other shape memory alloy or metal. The frame **920** may be a dissimilar material as that of the expandable member **940**. The frame **920** may be tubular with a wall circumferentially defining a central axis. The frame **920** may include angled segments as shown, and/or other segments, configurations, etc. The frame **920** as shown may be sinusoidally shaped, although its architecture could be of a diamond lattice or hexagonal lattice, for example. The frame **920** or portions thereof may incline radially outward with respect to the axis and/or with respect to the expandable member **940**. The frame **920** may pivot about pivot joints located at or near interfaces with the expandable member **940**. In some embodiments, fixed attachments are located at one or more of the joints between the frame **920** and the expandable member **940**, for example at the interfaces of abutting apices of the frame **920** and the expandable member **940**.

Anchors **930** may be metallic helical members. The anchors **930** may threadingly engage with the lower, i.e. distal, apices of frame **920**. The anchors **930** may wind through a series of holes through holes drilled in the distal ends or distal apices of frame **920** (more clearly indicated by reference numerals **1050** in FIGS. **10**, **11** and **12**). The frame **920** may include a series of distal apices formed by the frame **920** proximate the distal diameter. A series of holes in each of the distal apices may be sized and spaced to receive therethrough a corresponding helical anchor **930** for rotational engagement of the distal apex by the corresponding helical anchor **930**. The holes may be the same or similar to holes **1050** described for example with respect to FIG. **10**. The anchors **930** may be advanced distally, and in some embodiments retracted proximally, in a rotational or cork-screw type manner. The anchors **930** may extend distally relative to the frame **920**. For example, as the anchors **930** are rotated, the anchors **930** may move in the distal direction while the frame **920** is stationary. In some embodiments, the frame **920** may move distally while the anchors **930** move farther distally relative to the frame **920**. Thus, the frame **920** may be located in the preferred position and the anchors **930** may then be moved distally to secure into heart tissue while the frame **920** remains axially stationary or approximately axially stationary. This allows for better accuracy with positioning of the implant **910** because there is less movement of the frame **920** while the anchors **930** are being secured to heart tissue. Further, the anchors **930** engage the frame **920**, as described, for example through the series of holes in distal apices of the frame **920**. This allows for a secure attachment between the anchors **930** and the frame **920** without the need for additional structure or features. The arrangement of the holes and the corresponding receiving of the anchor **930** therethrough in each apex allows for an axially secure engagement of the anchor **930** and the frame **920** while still allowing for movement of the anchor **930** by driving it with the driver **952**. By axially secure it is meant that the anchor **930** will not move axially relative to the frame **920** in the absence of sufficient rotational force acting on the anchor **930**, such that the anchor **930** and frame **920** are rotationally secured together after removal of the rotational force from the driver **952** thereby impeding further axial movement of the anchor **930** relative to the frame **920**. The configuration of the series of holes in the frame **920** and the helical shape of the anchors **930** allows for such advantages. In FIG. **9**A, the anchors **930** are shown extended distally, for example in the final stage of deployment into cardiac tissue proximate the mitral annulus. The mitral annulus is that region of transition from the left atrium to the left ventricle and proximate and above the area where the leaflets of mitral valve **170** (see FIG. **5**) hinge from the left ventricle.

The implant **910** may include the expandable portion or member **940**. The expandable member **940** may be stent-like. The expandable member **940** may be tubular with a wall circumferentially defining a central axis. The expandable member **940** may include angled segments as shown, and/or other segments, configurations, etc. While shown in the shape of a sinusoid, the expandable member **940** may otherwise have a diamond lattice or hexagonal lattice architecture, for example. The expandable member **940** may be a dissimilar material as that of the frame **920**. The expandable member **940** may be made of metallic alloys such as stainless steel, cobalt chromium, platinum iridium and the like. The expandable member **940** may be collapsed or crimped for insertion into a delivery system and forcibly expanded, so as to undergo plastic deformation, to invert the frame **920**. As shown in FIG. **9**A, expandable member **940** may be integral with frame **920**, for example a unified, monolithic portion or region of the frame **920**. In some embodiments, the expandable member **940** is fixedly attached to frame **920** by bonding, welding, sutures, metallic bands crimped on to each structure, or otherwise connected in a fixed relationship to frame **920**. In some embodiments, the expandable member **940** can have other coupling interactions with the frame **920**, such as a friction fit, expansive force keeping the frame **920** secured with the expandable member **940**, etc.

Implant **910** is loaded into the distal end of a delivery system (not shown), by compressing or collapsing the frame **920**. Anchors **930** would be initially retracted for loading and delivery. Once positioned in a desired location proximate the mitral valve annulus, frame **920** is advanced out of the delivery system and its distal apices are abutted to the target heart tissue for anchor placement. The helical anchors are then advance, by rotation thereof, into the target cardiac tissue thereby anchoring implant **910** into the region of the mitral valve annulus. Implant **910** is then fully released from the delivery system.

After implant **910** is fully released from the delivery system, expandable member **940** is then forcibly expanded, such as by a dilatation balloon, causing frame **920** to invert. Inversion of frame **920** causes the anchor bearing distal end of frame **920** to taper or contract, causing the mitral valve annulus to reduce in size thus limiting the mitral valve regurgitation.

FIG. **9**B is another embodiment of an implant **912**. The implant **912** may have the same or similar features and/or functionalities as the implant **910**, and vice versa, except as otherwise noted. The implant **912** comprises the expandable member **940** and piercing members or anchors **930**. A frame **922** extends circumferentially about a central longitudinal axis. The frame **922** is formed to have as its free or unconstrained configuration somewhat opposite to that of the frame **920** of the implant **910**. For example, as shown the lower, distal end as oriented, the end engaging anchors **930**, may be smaller in diameter than the opposite upper, proximal end of the frame **922**. The frame **922** may therefore incline radially inward relative to the central axis and/or relative to the expandable member **940**. The frame **922** and the expandable member **940** may be formed of dissimilar materials. The frame **922** may be formed of similar materials as the frame **920** described with respect to FIG. **9**A.

To perform the procedure of influencing the size of the mitral annulus, for example for treating the patient's mitral regurgitation, the expandable member **940** and the larger, proximal end of frame **922** are compressed or crimped and loaded into the distal end of a delivery system (not shown). This action also causes the distal or narrower end of frame **930** to invert. Such inversion must be restrained for loading into the delivery system.

Once positioned in the desired location proximate the heart valve annulus, such as the mitral valve annulus, the frame **922** is advanced out from the distal end of the delivery system, inverting as it is no longer constrained by the delivery system and expandable member **940** remains in the crimped configuration. The distal ends or distal apices of frame **922** are then positioned in abutting relationship to the target cardiac tissue proximate the mitral valve annulus. Helical piercing members **930** are then rotationally advanced into and in engagement with the target heart tissue in a manner very similar to the helical screw of a corkscrew advancing through a cork. The expandable member **940** is then expelled from the delivery system and forcibly expanded, for example by dilatation balloon which balloon could be an integral component of the delivery system. Expansion of the stent-like expandable member **940** causes frame **922** to revert to its nominal or free state thereby causing its distal apices and helical anchors to become narrower in diameter reducing the size of the mitral annulus and limiting the degree or extent of mitral regurgitation.

FIGS. **10**, **11** and **12** are various views of another embodiment of an implant **1010**. In this embodiment, the implant **1010** has a frame **1020** and an expandable member **1040** that are not formed as an integral implant, as for example in

FIGS. **9**A and **9**B. Rather expandable member **1040** is positioned within frame **1020** proximate the proximal end thereof. Frame **1020** is made from a nickel titanium alloy, such as Nitinol, whereas expandable member **1040** is preferably made of metallic alloys such as stainless steel, cobalt chromium, platinum iridium and the like.

FIG. **10** shows frame **1020** in its free or unconstrained state with expandable member **1040** crimped and positioned within frame **1020**. One or more holes **1050** are pre-drilled in the distal ends or apices of frame **1020** and oriented to accommodate the pitch of helical anchors (not shown for clarity) such as the anchors **930** of FIGS. **9**A and **9**B. The anchors **930** may be rotated through the holes **1050** to advance the anchors **930** distally, i.e. downward as oriented in the figure. In some embodiments, the anchors **930** may be rotated in the opposite direction through the holes **1050** to retract the anchors **930** in the opposite, proximal direction. FIG. **11** shows the frame **1020** in a constrained configuration and implant **1010** ready for loading into the distal end of a delivery system (not shown). FIG. **12** shows implant **1010** in what would be its deployed configuration. While expandable member **1040** is shown to have a diamond like lattice configuration, it is contemplated that it may also take the form of a sinusoid or a hexagonal configuration.

Delivery of implant **1010** may be conducted in similar respect to the embodiment of FIG. **9**A. More specifically, implant **1010** is loaded into the distal end of a delivery system (not shown), by compressing or collapsing frame **1020** as shown in FIG. **11**. Once positioned in a desired location proximate the mitral valve annulus, frame **1020** is advanced out of the delivery system and its distal apices are abutted to the target heart tissue for anchor placement. The helical anchors (not shown) are then advance, by rotation thereof, into the target cardiac tissue thereby anchoring implant **1010** into the region of the mitral valve annulus. Implant **1010** is then fully released from the delivery system.

After implant **1010** is fully released from the delivery system, expandable member **1040** is then forcibly expanded, such as by a dilatation balloon, causing frame **1020** to invert as shown in FIG. **12**. Inversion of frame **1020** causes the anchor bearing distal end of frame **1020** to taper or contract, causing the mitral valve annulus to reduce in size thus limiting the mitral valve regurgitation.

FIG. **13** shows an exemplary steerable delivery system **950**, including for example a catheter or catheter lumen, suitable for delivery of the various implant embodiments described herein. FIG. **13** depicts an embodiment of the implant **1010** of FIGS. **10**-**12**, but it is understood that the delivery system **950** can be used to delivery other implants, including but limited to the implant **912** of FIG. **9**B and the implant **910** of FIG. **9**A, the latter of which is further shown in and described with respect to FIG. **14**. For example, a similar delivery system **950** may be used for the implant **912** embodied in FIG. **9**B. For brevity and since the expandable members are different between the aforementioned embodiments, the expandable members **1040** are not shown in FIG. **13**.

The delivery system **950** may include a tube or tube-like structure having one or more lumens extending therethrough. For instance, the delivery system **950** may include an elongated tube or delivery catheter having one or more openings, i.e. lumens, extending therethrough and configured to receive therein, or having therein, corresponding features of the delivery system **950**, including but not limited to the guide wire **160**, the catheter **140**, one or more of the drivers **952**, and the intracardiac echo catheter **960**. In some embodiments, the delivery system **950** includes a delivery catheter having a lumen to guide the delivery catheter over the guide wire, another lumen or lumens that include(s) the rotatable drivers **952**, the implant **912** in a constrained delivery configuration located at a distal end of the delivery catheter, and a sheath covering the distal end of the catheter. Delivery system **950** is advanced transfemorally, either through the femoral vein and transeptally to the left atrium or through the femoral artery up through the aortic arch and then passed the aortic and mitral valves into the left atrium. Once positioned above mitral annulus and proximate the target heart tissue, the implant is partially released, releasing the frame portion **920**, **1020**. Frame **920**, **1020** is now unconstrained and able to return to its nominal or free state as shown in FIG. **13**.

Helical piercing members **930** are then rotationally advanced into the target cardiac tissue, anchoring the implant to the interior heart wall above the mitral annulus. The implant and expandable member **940**, **1040** is then released from delivery system **950**. At such time, the stent like member **940**, **1040** is forcibly expanded causing the frame **920**, **1020** to invert. The distal end of apices and helical anchors **930** are then cinched inwardly reducing the diameter of the distal end of frame **920**, **1020** causing a corresponding reduction in the size of the mitral annulus. This reduction in size of the mitral annulus, allows the mitral valve leaflets to better, if not completely, coapt reducing the severity of the patient's mitral regurgitation.

In a further embodiment of the present invention, an intracardiac echo catheter **960** is incorporated in delivery system **950**. Catheter **960** could be included in a lumen of delivery system **950**, either internally as shown, or alongside implant delivery system **950**. By rotating catheter **960** within the left atrium and proximate the mitral valve annulus, the relative position of the implant with respect to the mitral valve leaflets can be determined. This allows for accurate positioning of helical anchors **930** into the target heart tissue proximate the mitral annulus without piercing the mitral valve leaflets.

FIG. **14** depicts the steerable delivery system **950** being used to deliver the implant **910** of FIG. **9**A. The description of the delivery system **950** above with respect to FIG. **13** applies to use of the system **950** with the implant **910**, and vice versa, except as otherwise noted. As shown in FIG. **14**, the implant **910** thus includes the frame **920** and expandable member **940**, shown as integral with the frame **920**. In some embodiments, the implant **910** may only include the frame **920**. The delivery system **950** may or may not include the intracardiac echo catheter **960**, as described above.

As shown in FIG. **14**, a plurality of rotational drivers **952** extends out through a distal opening of a lumen of the delivery catheter and/or sheath of the delivery system **950**. Each driver **952** may extend through a corresponding lumen of the delivery system **950**. In some embodiments, more than one or all of the drivers **952** may extend through the same lumen of the delivery system **950**. A guide wire, such as the guide wire **160**, may also be incorporated into the delivery system **950**, and may extend through a lumen of the delivery system **950**.

The drivers **952**, only some of which are labelled for clarity, are each engaged with a corresponding rotational anchor **930**. The drivers **952** may be pre-engaged with the anchors **930** within the delivery catheter of the delivery system **950** before insertion of the distal end of the delivery system **950** into the atrium. The drivers **962** may be mechanically engaged with the anchors **930** in a variety of suitable approaches. For example, the drivers **962** may have a clevis type fitting as shown configured to surround the proximal end of the anchors **930**. The drivers **952** may extend over, on, under, etc. the proximal ends of the anchors **930** and then be rotated to transmit rotation to the anchors **930**. In some embodiments, the anchors **930** may have recesses or other tool-receiving portions engaged by the drivers **952** such that rotation of the drivers **952** is transmitted to the anchors **930**. In some embodiments, the drivers **952** may include socket type fittings that surround the anchors **930**. In some embodiments, the anchors **930** may have internally-threaded blind holes through which corresponding externally-threaded members of the drivers **952** are received. These are merely some examples of how the drivers **952** may be engaged with the anchors **930**, and other suitable approaches may be implemented. With the implant **910** in position for anchoring to the annulus, a proximal end of the drivers **962** may be manipulated by the user, for example rotated by the surgeon, to rotate the anchors **930** and thereby advance the anchors **930** into heart tissue, as described herein, to secure the implant **910** with the heart tissue. Each driver **952** may be actuated simultaneously, some may be actuated simultaneously, or they may be actuated sequentially. The anchors **930** may extend distally relative to the frame, as described herein.

FIGS. **15**A-**15**D show sequential views of an embodiment of a transcatheter delivery system for delivering the implant **910** showing an embodiment of a method for the delivery, positioning and anchoring of the implant **910** for resizing the native valve annulus. The various delivery systems as described herein may be used. As shown, the delivery system may include the sheath **150**, the catheter **140** and the guide wire **160**. The sheath **150**, the catheter **140**, the guide wire **160** and the implant **910** are configured for transcatheter delivery of the implant **910** to the heart. The implant **910** may be delivered by the delivery system percutaneously by catheter through an opening in the femoral vein. The implant **910** may be advanced through the femoral vein into the vena cava and into the right atrium. The distal ends of the sheath **150**, catheter **140**, and guide wire **160** are configured to extend through the opening in the femoral vein, through the femoral vein and into the right atrium of the heart, and through the septum of the heart into the left atrium.

As shown in FIG. **15**A, the guidewire **160** may be advanced through the septum separating the upper chambers of the heart and the sheath **150** and catheter **140** may be advanced to that position along the guide wire **140**. The distal end of the catheter **140** is advanced to a position above the heart valve annulus, for example, the mitral valve annulus, as shown in FIG. **15**B. FIG. **15**C shows the implant **910** expelled from the distal end of the sheath **150** above and proximate to the mitral valve annulus. In some embodiments, a series of images may be taken, for example with an intracardiac echo catheter, to properly position the anchors **930** for insertion into the mitral valve annulus tissue. As shown in FIGS. **15**C and **15**D, the anchors **930** may be rotationally engaged by rotational drivers of the delivery system, such as the drivers **952** described herein, for rotation and distal advancement of the anchors **930** into the heart valve annulus. In some embodiments, a circumferential image may be captured to confirm that all anchors **930** are appropriately placed and anchored in the mitral valve annulus tissue above the mitral valve leaflets. If one or more anchors **930** are not positioned or anchored properly, the drivers **952** may reverse the direction of rotation to rotationally retract the anchors in the proximal direction. The anchors **930** can then be repositioned and re-anchored prior to removal of the drivers **952**.

Though a particular path of transcatheter delivery is described with respect to FIGS. **15**A-**15**D, a variety of other delivery paths and approaches may be employed, including but not limited to the paths shown and described with respect to FIGS. **1**A-**1**F, trans-apical delivery, etc. In addition, any of the features and/or functionalities of the delivery system and associated methods described with respect to FIGS. **1**A-**1**F may be incorporated with respect to the delivery system and methods described with respect to FIGS. **15**A-**15**D, and vice versa. Therefore, for example, with regard to the delivery system and methods described with respect to FIGS. **15**A-**15**D, the implant **910** may "invert" as described herein, an expandable or fixed ring **320** may be utilized as described, the location ring **120** may be inserted below the valve, etc.

This disclosure encompasses all changes, substitutions, variations, alterations, and modifications to the example embodiments herein that a person having ordinary skill in the art would comprehend. Similarly, where appropriate, the appended claims encompass all changes, substitutions, variations, alterations, and modifications to the example embodiments herein that a person having ordinary skill in the art would comprehend. Moreover, reference in the appended claims to an apparatus or system or a component of an apparatus or system being adapted to, arranged to, capable of, configured to, enabled to, operable to, or operative to perform a particular function encompasses that apparatus, system, component, whether or not it or that particular function is activated, turned on, or unlocked, as long as that apparatus, system, or component is so adapted, arranged, capable, configured, enabled, operable, or operative. For example, various embodiments may perform all, some, or none of the steps described above. Various embodiments may also perform the functions described in various orders.

Although the present disclosure has been described above in connection with several embodiments; changes, substitutions, variations, alterations, transformations, and modifications may be suggested to one skilled in the art, and it is intended that the present disclosure encompass such changes, substitutions, variations, alterations, transformations, and modifications as fall within the spirit and scope of the appended claims.

The invention claimed is:

1. A method for reducing the diameter of a mitral valve, the method comprising:

inserting an implant proximate a mitral valve, the implant comprising a tubular body having an upper portion and a lower portion and a plurality of piercing members extending from the lower portion;

engaging the plurality of piercing members with tissue proximate the mitral valve on a first side of the mitral valve;

coupling at least one of the plurality of piercing members with a location ring that is positioned on a second side of the mitral valve; and

reducing the diameter of the lower portion of the tubular body of the implant to reduce the diameter of the mitral valve.

2. The method of claim **1**, further comprising transitioning the tubular body from a collapsed structural configuration allowing the tubular body to fit into a sheath to an expanded structural configuration to engage tissue proximate the mitral valve.

3. The method of claim **2**, wherein transitioning the tubular body to an expanded structural configuration further comprises applying an expansive force to the tubular body.

4. The method of claim 3, wherein applying an expansive force comprises applying an expansive force via a ring positioned within the tubular body.

5. The method of claim 4, wherein the ring is expandable, the method further comprising expanding the expandable ring to transition the tubular body to the expanded structural configuration.

6. The method of claim 1, wherein engaging tissue further comprises applying vibration to at least one of the plurality of piercing members, the tissue proximate the mitral valve on a same side of the mitral valve as the implant, or the tissue proximate the mitral valve on a side of the mitral valve opposite the implant.

7. The method of claim 1, wherein at least one of the plurality of piercing members is covered during the insertion of the implant proximate the mitral valve.

8. The method of claim 1, wherein at least one of the plurality of piercing members engages the tissue proximate the mitral valve before another of the plurality of piercing members.

9. The method of claim 1, further comprising positioning the implant where the mitral valve hinge meets the left ventricle and the left atrium meets the mitral valve.

10. The method of claim 1, further comprising viewing the location ring via fluoroscopy or echo guidance to confirm a positive location for the implant to be located with respect to the mitral valve annulus.

11. The method of claim 1, further comprising coupling at least one of the plurality of piercing members to the location ring by extending the piercing member through the heart valve annulus to connect the piercing member with the location ring.

12. The method of claim 1, wherein:

engaging the plurality of piercing members with tissue proximate the mitral valve is performed from within the left atrium; and

coupling at least one of the plurality of piercing members with a location ring comprises engaging the location ring within the left ventricle.

13. A system comprising:

a guide wire;

a sheath for sliding over the guide wire;

an implant for delivery to a body by traveling through the sheath and along the guide wire,

the implant comprising a tubular body comprising an upper portion and a lower portion;

a plurality of piercing members connected to the lower portion of the tubular body; and

a location ring configured to be located on a side of the mitral valve opposite the implant and viewable via imaging guidance to confirm the location of the implant with respect to the location ring.

14. The system of claim 13, wherein at least one of the plurality of piercing members is coupled to the location ring.

15. The system of claim 13, wherein at least one of the plurality of piercing members is coupled to the implant with a hinged attachment.

16. The system of claim 13, further comprising a catheter configured to be introduced through the sheath for engaging the plurality of piercing members to cause the plurality of piercing members to penetrate the tissue proximate the mitral valve.

17. The system of claim 13, where the location ring is configured to be removed from the heart after the implant is positioned and the piercing members penetrate the heart valve annulus.

18. The system of claim 13, further comprising an intra-cardiac echo catheter for visualizing a position of at least one of the implant or the location ring.

19. An implant for reducing the size of a heart valve annulus, the implant comprising:

a tubular body having an upper portion and a lower portion, the upper portion configured to be free in the left atrium and the lower portion configured to engage tissue around a heart valve, the tubular body including a plurality of piercing members connected to the lower portion of the tubular body and configured to engage tissue proximate the heart valve annulus; and

a location ring configured to be located on a side of the mitral valve opposite the tubular body;

wherein at least one of the plurality of piercing members is positioned to first extend through tissue of the mitral valve and then to couple with the location ring.

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